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In The

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

BARR LABORATORIES, INC.,
and
APOTEX, INC., and BERNARD C. SHERMAN,
and
GENEVA PHARMACEUTICALS, INC.,
and
INTERPHARM, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Did the Court of Appeals err in invalidating Petitioner's basic patent on the antidepressant drug Prozac on the ground that the 1974 discovery claimed by the patent was "obvious" when compared to a second patented discovery that was not even made until 1983, years after the 1974 discovery was first publicly disclosed as "prior art"?

2. Did the Court of Appeals err in ruling that Petitioner was not entitled, despite the plain language of 35 U.S.C. § 253 and uniform precedents applying it, to preserve the validity of its basic Prozac patent by "disclaiming" the final seven months of its patent term held by the court to be an "unjustified timewise extension" of patent exclusivity?

PARTIES AND CORPORATE DISCLOSURE

There are no named parties other than those stated in the caption. Eli Lilly and Company has no parent company and no subsidiaries or affiliates that have issued shares to the public.

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PETITION FOR A WRIT OF CERTIORARI

Eli Lilly and Company ("Lilly" or "Petitioner") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals is reported at 251 F.3d 955 (Fed. Cir. 2001) and is reprinted in the appendix hereto ("App.") at 1a. The court of appeals order denying rehearing and rehearing *en banc* is not reported and is reprinted at App. 95a. The initial opinion of the court of appeals was reported at 222 F.3d 973 (Fed. Cir. 2000) and is reprinted at App. 57a. This initial opinion was vacated by the *en banc* court of appeals in an unreported order reprinted at App. 37a. The unpublished opinion of the district court is reprinted at App. 86a.

JURISDICTION

Judgment of the court of appeals was entered on May 30, 2001, and the order denying rehearing and rehearing *en banc* was entered on July 18, 2001. This Court has jurisdiction under 28 U.S.C. § 1254.

PERTINENT STATUTORY PROVISIONS

Relevant provisions of the patent statute are codified at 35 U.S.C. §§ 100(b), 101, 102, 103, and 253, and are reprinted at App. 101a. Of particular relevance to the first question presented is Section 103(a), which in pertinent part provides:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Section 253 is especially relevant to the second question presented. In pertinent part, it provides that "any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted."

STATEMENT OF THE CASE

A. Introduction

In the decision below, a panel of the Federal Circuit invalidated Lilly's basic patent for the revolutionary antidepressant drug Prozac, prematurely ending Lilly's marketing exclusivity two and a half years (and at least $4 billion in sales) before the expiration of the patent's statutory term in December 2003. No less startling than the result of the decision was the reasoning that yielded it: the panel determined that the 1974 discovery claimed in the basic Prozac patent was "obvious" when compared to a discovery that was not even made until 1983.

At the heart of the case are two patents. One of these patents (the "Molloy" patent) claims Lilly's basic discovery that Prozac's active ingredient, fluoxetine hydrochloride, is especially effective at inhibiting uptake of serotonin in the brain. This discovery, first publicly disclosed by Lilly in the 1970s, led to a host of follow-on inventions by Lilly and by others. The second patent (the "Stark" patent) claims Lilly's 1983 discovery of a "new use" for Prozac – that Prozac, in appropriate doses, treats anxiety in humans.

The panel held that Lilly's Molloy patent ran afoul of the doctrine of "obviousness-type double patenting," a judge-made rule designed to prevent one patentee from obtaining two or more separately valid patents for the same invention or an obvious variation of the same invention. The "double patenting" doctrine exists to prevent such patents from having separate patent terms that

might otherwise create "an extension of the patent right beyond the statutory time limit." *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998).

Central to the panel's decision was the fact that the basic Molloy patent issued seven months later than the Stark "new-use" patent and, thus, has a statutory term that will expire seven months after the statutory term for the Stark patent will expire. Hence, according to the panel, the effect of owning two patents rather than one patent is to provide Lilly with an extended period of exclusivity seven months longer than it would have been if Lilly had been issued only the Stark patent. The court believed this extra seven months constituted an "unjustified timewise extension" of Lilly's period of exclusivity. The crux of this determination was that the basic Molloy invention was "obvious" in view of the Stark new-use invention.

The problem with the panel's ruling is that it directly contradicts the *statutory* nonobviousness test for separate patentability. 35 U.S.C. § 103. Section 103 of the patent statute specifically conditions patentability for every invention on the requirement that the invention be nonobvious when compared to the "prior art" respecting that invention – that is, the state of knowledge existing "at the time the invention was made." *Id.* But instead of inquiring, as both the statute and commonsense dictate, whether the Molloy invention was nonobvious in light of *previously discovered* inventions in its "prior art," the panel asked the totally illogical question whether the Molloy invention was nonobvious in light of a *later-discovered*, follow-on invention derived directly from the Molloy invention – in effect, *the subsequent art.*

Under the statute, when an inventor shows that he has made a follow-on discovery that is a "nonobvious" innovation in view of the "prior art," including his own earlier

discoveries, he is entitled to a separate patent on his follow-on invention. In other words, if a later-discovered invention is nonobvious in view of an earlier-discovered "prior art" invention, then the two inventions are "patentably distinct" from one another, permitting a separate patent to issue for the later discovery. If the inventions are not "patentably distinct" in this manner, only one patent may validly issue. In short, then, whenever Section 103 applies to assess whether an invention is nonobvious over an earlier "prior art" invention, it necessarily disposes, once and for all, of the issue of "double patenting" – *i.e.*, two patents issuing for the same or obvious variations of the same invention – between those two patents. Indeed, uniform legal precedent stretching back more than a century confirms that if this nonobviousness test applies to two inventions and is satisfied, the statute dictates that two separate patents must issue, and that no "double patenting" can exist.

In accord with this straightforward statutory scheme, the Patent and Trademark Office ("PTO") specifically determined that the new use described for Prozac in the Stark patent was nonobvious in light of the prior art, including the earlier-discovered basic invention claimed in the Molloy patent, and the PTO therefore issued the Stark new-use patent. Because the Stark new-use invention was nonobvious in light of the Molloy "prior art" invention, the patent statute clearly and incontrovertibly dictated that the two inventions cannot constitute double patenting, and that, because *both* inventions were nonobvious when compared to their respective prior art, two valid patents should issue.

The panel, by contrast, did not ask whether Lilly's later-discovered new-use invention (Stark) was obvious in light of its basic invention (Malloy), but instead asked *whether Lilly's earlier-discovered basic invention was obvious*

in light of its later-discovered new-use invention. But this question, whether an invention was obvious in light of another invention that did not yet exist, is akin to asking whether the parent was born after the child.

A basic "prior art" invention cannot be "nonobvious" in view of a later-discovered new-use invention. A new-use invention that builds upon the innovations claimed in the earlier-discovered basic patent will inevitably embody those earlier-discovered innovations, so that, if the two discoveries are looked at in reverse order of their discovery, the basic invention will *necessarily* be "obvious" in light of the new use. In other words, the court applied a judge-made test for separate patentability that literally *reverses* the statutory test, and in so doing doomed Lilly's basic Molloy patent to fail.

The Federal Circuit's error is rooted in the fact that it focused not on the order in which the two *inventions were discovered* but rather on the order in which the resulting *patents issued*. As noted, Lilly's basic Molloy patent issued seven months after the Stark new-use patent, and therefore was due to expire seven months later – in December of 2003. But the order of patent issuance has no relevance to the fundamental precept of patent law that is at stake in this case: two inventions are each separately patentable if the later-discovered invention is nonobvious in light of the earlier "prior art" invention. This statutory test is wholly indifferent to the dates on which the patents on those two inventions issue. And where this statutory test is satisfied and the statute dictates that two patents may issue, the judge-made doctrine of double patenting does not and cannot apply to produce a different result. Thus, the decision below overturned a result mandated by the patent statute, and the profound ramifications of the Federal Circuit's error amply warrant this Court's review.

But the Federal Circuit did not stop there. Even if the decision below were somehow correct, and Lilly's basic Molloy invention was properly declared obvious in light of Lilly's subsequent new-use invention, it is well-established that Lilly is entitled to preserve the validity of its patent by simply "disclaiming" the seven months of "unjustified" extension of patent protection contained in the term of the basic patent, from May 2003 to December 2003. Not only is this result compelled by logic – these seven months, after all, caused the court to reach its result in the first place – it is also unambiguously guaranteed by statute and decades of uniform precedent. *See* 35 U.S.C. § 253.

Inexplicably, however, the Federal Circuit preemptively ruled that Lilly was not entitled to avail itself of the well-settled remedy of disclaiming the excess term of the later-expiring patent. Instead, the court ruled that Lilly must lose the *entire* protection on its basic Prozac patent. This was the Federal Circuit's second major legal error warranting review by this Court.

B. The Subject Matter of the Dispute

Both of the patents at issue in this case issued in 1986, and their 17-year terms are therefore due to expire in 2003. Lilly first began to sell Prozac in the United States in 1988, and at the time of the Federal Circuit decision, Lilly's Prozac sales exceeded two billion dollars per year. Respondents and other generic drug manufacturers have sought to market generic versions of Prozac before Lilly's patents expire.

Although widely known as the most prescribed antidepressant drug in the world, subsequent "new use" discoveries have shown that Prozac can also be effective in treating other disorders, including anxiety, obsessive compulsive disorder, and bulimia. It is Lilly's patent on

the discovery of Prozac's "new use" in treating anxiety that was relied upon by the Federal Circuit to invalidate Lilly's basic Molloy patent.

C. Lilly's Prozac Patents

In 1974 Lilly filed a patent application setting forth a number of innovative discoveries, all of which related to its development of what would later become Prozac. This application became the subject of complex and lengthy proceedings before the PTO. The PTO took the position that there were multiple inventions disclosed in the original application, and required "restriction" of the original application to just one of the disclosed inventions, pursuant to 35 U.S.C. § 121. Thus, the PTO required Lilly to pursue a number of different patents, through what are known as "divisional applications," relating to different aspects of the basic discoveries underlying the Prozac invention.

In response to this PTO requirement, Lilly initially prosecuted claims directed to the disclosed chemical compounds. These proceedings were severely complicated by numerous patentability inquiries from the PTO that required numerous responses by Lilly and three appeals to the PTO Board of Appeals.

Promptly upon completion of the PTO's examination of these compound claims in 1986, Lilly undertook a review of its original application to determine whether there remained any disclosed inventions that should be claimed. Such a review at the close of patent prosecution was and is customary. That review revealed that the basic invention of using fluoxetine to block serotonin uptake in brain neurons had not yet been patented. Accordingly, claims to that invention were promptly presented and the Molloy patent issued on December 2, 1986.

Given the complexity of the discoveries underlying Prozac, this twelve-year prosecution history is not at all unusual. Indeed, a lengthy prosecution period is typical where any *one* of the following factors is present: (1) the application discloses multiple inventions resulting in PTO requirements to restrict the initial application to only one of the disclosed inventions;[1] (2) PTO rejections must be appealed to the PTO Board of Appeals;[2] or (3) the invention is basic and the patent claims are broad.[3] Given that *all* of these factors were present here, the patent prosecution history of Prozac is not surprising, and Respondents have never asserted that Lilly may be guilty of laches or of inequitable conduct designed intentionally to delay issuance of the Molloy patent.

In addition to the basic patents that issued on the basic discoveries underlying the Prozac invention, numerous patents have issued on a variety of follow-on, "new-use" discoveries that have grown out of the initial breakthroughs. Indeed, the public disclosure of Lilly's

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[1] *See, e.g., Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 357 (Fed. Cir. 1968) (14-year delay resulting in part from restriction requirement); *Applied Materials, Inc. v. Gemini Research Corp.*, 835 F.2d 279 (Fed. Cir. 1988) (15-year delay resulting in part from restriction requirement); *In re Henriksen*, 399 F.2d 253, 262 (C.C.P.A. 1968) (20-year delay resulting from prosecution of continuing applications).

[2] *See, e.g., General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992) (10-year delay resulting from appeal to PTO Board of Appeals).

[3] *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 727 (6th Cir. 1897) (Taft, J.) ("[T]he course of an application for a generic or broad invention may legitimately take longer in its course through the patent office than a comparatively unimportant improvement on that invention.").

basic inventions led to an explosion of research and discovery in this field. More than 5,500 research papers have been published on fluoxetine, and at least eleven additional United States patents were sought and issued for nonobvious new medical uses of fluoxetine. Only two of these new-use inventions were discovered and patented by Lilly, while nine were discovered and patented by others.

One of these new-use discoveries was the discovery by Lilly's Dr. Stark, made years after Molloy's basic inventions had been published as "prior art," that fluoxetine could be used to treat anxiety in humans. Stark's discovery was embodied in a 1983 patent application that referred the PTO specifically to the published text of Molloy's basic patent application as a related "prior art" invention. Thus, all aspects of each of Molloy's breakthrough discoveries were disclosed as "statutory prior art" against which Stark's claims had to be nonobvious in order to be patentable.

Because of its narrow scope, Stark's patent application did not encounter the examination complexities encountered by the broad, basic application of Molloy. The PTO determined that Stark's new-use invention was both novel, 35 U.S.C. § 102, and nonobvious, 35 U.S.C. § 103, in light of Molloy's earlier invention, and Respondents have never challenged the correctness of that determination. Likewise, the PTO determined that the basic Molloy invention was novel and nonobvious in light of its "prior art." Because the statutory test for separate patentability had been satisfied, the PTO found that Stark and Molloy were entitled to separate patents. In this regard, Stark received the same treatment as the inventors named on at least nine other patents issued by the PTO to scientists not employed by Lilly for separately patentable new uses of fluoxetine.

Stark's new-use improvement patent issued in May of 1986 and was assigned to Lilly. Molloy's basic patent on the special effectiveness of fluoxetine in blocking serotonin uptake in brain neurons issued seven months later, and was also assigned to Lilly. While Lilly's basic Molloy patent has allowed Lilly to market Prozac with exclusivity since 1988, the Stark invention, use of fluoxetine to treat human anxiety, has never even been approved by the Food and Drug Administration ("FDA"). Accordingly, the Stark patent, ironically, has never had any relevance at all to the time during which Lilly could exclusively market Prozac. Indeed, because the Stark patent was commercially and legally irrelevant to Prozac, Lilly disclaimed the Stark patent claims in 1998 in an effort to simplify the issues for trial.

D. Proceedings Below

The case began in 1996 when, prior to the expiration of Lilly's Prozac patents and after Lilly had been marketing Prozac in the United States for only eight years, Respondent Barr Laboratories ("Barr") applied for permission from the FDA to market a generic version of Prozac. Lilly asserted its patent rights against Barr in this suit seeking injunctive relief. Barr challenged the validity of Lilly's Molloy patent on the theory, among others, that it was invalid under the doctrine of "obviousness-type double patenting."

The trial court found that the Respondents' double patenting theories constituted "a confusing amalgamation of broad patent law principles that are not clearly applicable to the [double patenting] issues before the Court" and that the Respondents had "failed to provide any authoritative, reliable scientific opinion" to support their theory. App. 92a & 93a. Accordingly, summary judgment was entered for Lilly on the double patenting issue.

On appeal, a panel of the Federal Circuit twice reversed the entry of summary judgment in Lilly's favor, striking down the Molloy patent as a matter of law. In its initial decision, the panel invalidated the basic Molloy patent on the ground that it constituted an "obvious" double patent in light of Lilly's prior discovery of a generic class of over five million chemical compounds that could be used to treat depression. App. 78a-85a. That prior discovery, according to the panel, rendered "obvious" Lilly's later discovery that one of those compounds, fluoxetine hydrochloride, was especially effective in doing so by virtue of its special effectiveness at blocking the uptake of serotonin in the brain. App. 81a-82a.

After Lilly filed a rehearing petition explaining why the "one in five million" discovery of this use for fluoxetine hydrochloride was a nonobvious discovery, the *en banc* Federal Circuit vacated the panel's decision and remanded the case to the panel for reconsideration. App. 37a. The panel then issued a second decision reaching the same result, but by a completely different analysis. App. 2a. This time, instead of asking whether the invention claimed in the Molloy patent was nonobvious in view of an *earlier* Lilly invention, the panel invalidated the Molloy patent by concluding that the invention it claims was "obvious" as compared to a *later-discovered*, improvement invention – namely, Stark's new-use discovery that fluoxetine is effective in the treatment of human anxiety.

This, according to the Federal Circuit, constituted obviousness-type double patenting notwithstanding that the new-use invention was not discovered by Stark until many years *after* the basic Molloy invention had been both discovered and published as "prior art." Inexplicably, the panel also ruled that Lilly was not allowed to use the well-established remedy in a double-patenting case of

terminally disclaiming that portion of its later-expiring patent that the court had concluded provides an unjustified timewise extension of exclusivity.

Circuit Judge Newman dissented from the court of appeals' refusal *sua sponte* to take the case *en banc*, arguing that double patenting could not be applied where, as here, one of the patented inventions was clearly statutory prior art to the other. App. 43a-49a. In addition, Judge Newman viewed as "unnecessary if not . . . punitive" the court's preemptive ruling that Lilly was not even entitled to protect the validity of its Molloy patent by disclaiming the last seven months of its term. App. 49a.

The Federal Circuit was not receptive to suggestions of continued error in its second opinion. Five *amici*, including the Federal Circuit's own bar association, sought to file briefs supporting Lilly's petition for rehearing of the second opinion. App. 51a-56a. The Federal Circuit denied the motions of the *amici* for leave to file those briefs, without awaiting an opposition brief, and denied Lilly's petition for rehearing on July 18, 2001. App. 51a-56a; App. 95a-96a.

This Petition followed.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW DIRECTLY CONTRADICTS THE STATUTORY REGIME FOR DETERMINING SEPARATE PATENTABILITY.

A. The Federal Circuit Applied a Judge-Made Test That Is the Mirror-Opposite of the Statutory Test.

The patent system is premised on the basic precept that a "new and useful" invention, 35 U.S.C. § 101, can be patented so long as it is novel, *id.* § 102, and nonobvious. *Id.* § 103. In particular, the statutory test for separate

patentability embodied in Section 103 requires the nonobviousness of the invention to be assessed by reference to the "prior art" – that is, the state of knowledge *"at the time the invention was made."* 35 U.S.C. § 103 (emphasis added).[4] Thus, when the prior art discloses a basic invention, the patent statute provides that the follow-on improvement or new-use invention is separately patentable if it is nonobvious in view of the earlier-discovered, basic invention.

The "nonobviousness" requirement operates as a statutory "double patenting" prohibition whenever one of the two patented inventions is prior art to the other. The statutory requirement prohibits issuing two valid patents if the *later-discovered*, follow-on invention is an obvious variation of the *earlier-discovered* prior art invention. Thus, only if the inventions are patentably distinct may two valid patents issue.

In this case, the Federal Circuit imposed a different, wholly unprecedented test for separate patentability that reverses the result mandated by the statute. The issue before the court of appeals was whether Lilly was entitled under the patent statute to own both the Molloy patent and the Stark patent. The Stark invention relates to a new use for the Molloy invention, and was therefore discovered *after* the discovery of the Molloy invention. Specifically, while the Molloy patent claims "a method of blocking the uptake of serotonin by brain neurons in animals" by administering fluoxetine, the Stark patent is directed to "a method for treating anxiety in a human by

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[4] The events that are cognizable as "prior art" under the statute are the events described in 35 U.S.C. § 102. *See Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). The text of Molloy's original patent application published in 1977 was "prior art" to Stark under 35 U.S.C. § 102(b).

administering an effective amount of fluoxetine." App. 25a.

It is not disputed that the basic Molloy invention was novel and nonobvious in light of the prior art that existed "at the time the invention was made." 35 U.S.C. § 103. Therefore, it was patentable under the statute. Nor is it disputed that the basic Molloy invention was "prior art" as to the subsequent Stark invention. Thus, the statute clearly resolves any issue of possible double patenting by providing that the two inventions are separately patentable – two patents rather than just one may be granted – so long as the later-discovered Stark invention is nonobvious in view of the earlier-discovered Molloy invention. As previously noted, in accordance with this clear statutory test, the inventions of Molloy and Stark were assessed by the PTO and found to be separately patentable. The correctness of the PTO's determination stands unchallenged. Accordingly, under the statute, two wholly separate patents, with two wholly separate and independent terms, may issue on these inventions, free from any possibility of double patenting.

The Federal Circuit, however, reversed the statutory nonobviousness inquiry, asking the opposite question – whether the *earlier-discovered* prior art invention was nonobvious in light of the *later-discovered* new-use invention. In other words, the court of appeals did not assess whether the Molloy basic invention was nonobvious in view of the "*prior* art" that existed "at the time the invention was made," as required by Section 103. Rather, it assessed the obviousness of the Molloy invention in view of the *subsequent* art that came into existence approximately nine years *after* the invention was discovered.

Plainly, as a matter of law and as a matter of common sense, an invention can be tested for obviousness under

Section 103 *only* against the inventions that precede it – the "prior art" – and not against inventions that have yet to be discovered. A basic invention will *always* be rendered obvious when it is compared, in hindsight, against a later-discovered "new use" invention that simply builds upon the basic invention. Thus, it was only by asking the nonsensical question of whether the basic Molloy invention was nonobvious from its later-discovered "new use" improvement that the court was able to invalidate the basic Molloy patent.[5]

The court of appeals asked this nonsensical question because it focused solely upon the order in which the Molloy and Stark patents issued, rather than the order in which the inventions were discovered. In doing so, the court rendered a decision that conflicts not only with the dictates of the patent statute, but also with venerable legal precedent. In 1897, Judge William Howard Taft of the Sixth Circuit faced an identical set of facts and an identical argument – that a patent on a basic invention should be invalid because it issued after, and was not patentably distinct from, a patent on a later-discovered

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[5] The decision below is especially ironic given that, as explained above, the FDA has never approved the use of the invention underlying Stark, and Stark's claims have thus in no way added to Lilly's ability to market Prozac with exclusivity. What's more, Lilly disclaimed all of the Stark claims in 1998, turning Stark into a pure "shell" patent, existing in name only. Given the hollow nature of the Stark patent and the reasoning that led the Federal Circuit to conclude that Molloy's 1974 discovery was obvious in view of Stark's 1983 discovery, the panel's decision amounts to a $4 billion fine against Lilly based on the perception, wholly unsupported in the record, that Lilly took too much time in prosecuting its Molloy patent. *See infra* Section I, C.

improvement on that invention.[6] *Thomson-Houston Elec. Co. v. Ohio Brass*, 80 F. 712 (6th Cir. 1897). Judge Taft rejected this argument, holding that "the date of the application, and not the date of the patent, controls in determining the legal effect to be given to two patents issued at different dates to the same inventor, and the order in which they are to be considered." *Id.* at 726.

Thus, the decision in *Ohio Brass* squarely considered and rejected the argument that "the later granting of the patent for the main invention extends the monopoly of the earlier improvement patent," *id.* at 726, and squarely held that "a patent for an improvement may expire before the patent for the main invention." *Id.* at 727. Moreover, in reaching this conclusion, Judge Taft explicitly considered this Court's decision in *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894), a case relied upon heavily by Respondents. Far

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[6] As Judge Taft stated:

> The argument runs thus: The monopoly of the first patent, the one for the improvement, can legally be of no longer duration than 17 years. But the improvement cannot be used except as applied to the main invention, and, as the later patent (the one for the main invention) does not expire until some time after the expiration of the patent for the improvement, the monopoly of the improvement patent is in fact extended until the expiration of the later patent (the one for the main invention), and so exceeds the statutory 17 years.

Ohio Brass, 80 F. at 726.

After perfectly summarizing the rationale that guided the Federal Circuit's decision in this case, Judge Taft rejected it: "[W]e cannot yield to the argument based on such a distinction, because we cannot accept its minor premise, to wit, that the later granting of the patent for the main invention extends the monopoly of the earlier improvement patent." *Id.*

from supporting Respondents' double-patenting argument, however, the *Miller* Court, as Judge Taft noted,

> distinctly recognize[d] . . . "that an inventor may make a new improvement on his own invention of a patentable character, for which he may obtain a separate patent," and "that a later patent may be granted where the invention is clearly distinct from and independent of the one previously patented." *It is, of course, true that, if an improvement is an invention separable from the generic invention, the latter is an invention distinct and separable from the improvement.* Hence it follows from . . . *Miller v. Manufacturing Co.* that *a patent for a generic invention is not avoided by the fact that a prior invention has been issued for a distinct improvement on that invention.*

Ohio Brass, 80 F. at 728, quoting *Miller v. Eagle Mgf. Co.*, 151 U.S. at 199 (emphasis added).

The panel's decision directly conflicts with Judge Taft's decision in *Ohio Brass*, effectively overturning, *sub silentio*, a precedent that has been recognized and followed as good law for more than a century. *See, e.g., In re Braat*, 937 F.2d 589, 593 (Fed. Cir. 1991) (citing *Ohio Brass* for proposition that "when a later filed improvement patent issues before an earlier filed basic invention, a double patenting rejection is only proper against the claims to the basic invention if the improvement is not patentably distinct from the basic invention"); *In re Stanley*, 214 F.2d 151, 155 (C.C.P.A. 1954) (citing *Ohio Brass* for its conclusion "that a later issued generic patent was not invalid because of an earlier issued but later filed improvement patent over the generic invention").

B. The Doctrine of Double Patenting Has Never Been Applied to Two Inventions That the Statute Dictates Are Separately Patentable.

It is not in dispute that the patent law abhors issuing two separate patents for the same or an obvious variation

of the same invention. The controversy here is instead centered on the operable test for determining whether two patented inventions are the *same or obvious variations of the same invention* such that double patenting has taken place.

By requiring that a claimed invention be nonobvious in view of the prior art at the time the invention was made, Section 103 ensures, subject only to one exception, that no more than one patent will issue for each, patentably distinct invention – that is, that there can be no "double patents." The *only* exception is the narrow circumstance in which the earlier invention is not included in the prior art of the later invention, so that the statutory test for patentable distinctness cannot be applied.

Ordinarily, of course, *all* earlier related inventions are included in the prior art against which a subsequent invention must be nonobvious in order to qualify for a separate patent under Section 103. Certain prior inventions, however, are statutorily carved out of the prior art, so that Section 103's nonobviousness test for separate patentability cannot be applied. Most notably, after an inventor discloses an original invention to the public, he is given one year under the statute in which to file as many patent applications as he wishes on his invention without having the public disclosure of that invention count against him as prior art. *See* 35 U.S.C. §§ 102(a) & (b). This exception from the statutory test is designed to facilitate the inventor's effort to patent that invention.

With respect to these "carve outs" from prior art, the judge-made doctrine of double patenting has been applied to ensure that all such patents claim patentably distinct inventions. Otherwise, a potentially unlimited number of patents on obvious modifications of a basic invention could be issued at different times, thereby

extending patent protection on a single patentable invention well beyond the 17-year term provided by statute.

Thus, it is solely to fill the statutory void created by the exceptional circumstance where the earlier invention was *not* included in the prior art, and for no other reason, that the judge-made doctrine of double patenting properly exists. Here, the earlier Molloy invention *was* included in the prior art, so that the follow-on Stark invention was subject to the statutory requirement that it be nonobvious in light of that original invention. Under these facts, the doctrine of double patenting simply does not apply. The Federal Circuit's use of double patenting in this case is therefore wholly unprecedented, as Circuit Judge Newman emphasized below. App. 43a-45a.

Indeed, neither the panel nor any of the Respondents has cited a single precedent finding double patenting in a case, like this one, in which the earlier-discovered invention was disclosed as part of the prior art against which the patentability of the later invention was measured. Lilly has found no such authority. The reason is clear: judge-made law cannot intrude into the area where Congress has supplied the complete test for separate patentability in the statutory scheme of Title 35. *See, e.g., Mobil Oil Corp. v. Higginbotham*, 436 U.S. 618, 625-26 (1978) ("There is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted."). As Judge Smith observed, concurring in *In re Braithwaite*, 379 F.2d 594, 602 (C.C.P.A. 1967) (Smith, J., concurring), "*If* Section 103 were applicable then obviously there would be no need for this type of 'double patenting.' " (emphasis added).[7]

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[7] Respondents sought to support the Federal Circuit decision on petition for rehearing by citing (1) this Court's decision in *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894), which involved two applications by the same inventor, neither of

The long-standing policies of the PTO confirm that the law of double patenting has been applied *only* where the statutory test for separate patentability is inapplicable. For example, as it became clear in the 1960s that certain prior inventions by third parties were going to be included in the prior art against which new inventions would have to be nonobvious in order to pass the statutory nonobviousness test, the PTO announced that it would *not* apply the doctrine of double patenting to these prior inventions. *See* 846 O.G. 687-88 (Jan. 9, 1967), *reprinted in* 5 LESTER HOROWITZ, PATENT OFFICE RULES AND PRACTICE rel. 72, Pub. 605 (Bender Aug. 1997). The PTO reasoned that double patenting is not necessary where the statutory nonobviousness test applies, explaining that "[i]n situations involving cases filed by different inventive entities, regardless of ownership, Sections 102 and 103 of 35 U.S.C. preclude the granting of two or more patents when directed to identical inventive concepts or when one of the concepts would be obvious in view of the other." *Id.*

Similarly, it was only when Congress narrowed the ground covered by Section 103's nonobviousness test in 1984 that the PTO practice on double patenting broadened to fill the resulting void. When Congress acted in

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which was prior art to the other, that both disclosed the exact same invention (*see, e.g., In re Allen*, 343 F.2d 482, 486-87 (C.C.P.A. 1965)); (2) *In re Blattner*, 245 F.2d 491 (C.C.P.A. 1957), which also involved two applications by the same inventor, neither of which was prior art to the other; and (3) *In re Borg*, 392 F.2d 642, 643 (C.C.P.A. 1968), in which the court specifically noted that the PTO had *not* "applied the [earlier filed] patent as evidence of prior art under 35 U.S.C. § 103." The Federal Circuit itself relied on *In re Berg*, 140 F.3d 1428 (Fed. Cir. 1998), and *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993). 251 F.3d at 968 n.7. Both of those cases also involved two applications by the same inventor, neither of which was statutory prior art to the other.

1984 to remove certain inventions from consideration as "prior art" under Section 103, *see* 35 U.S.C. § 103(c), the legislative history reflected the congressional expectation that the judge-made law of double patenting would be expanded to fill, as it had before, the area *not* dealt with by the patent statute. 130 CONG. REC. H10,525 (daily ed. Oct. 1, 1984), *reprinted in* 1984 U.S.C.C.A.N. 5827, 5834. The PTO did so in December of 1984. *See* 1050 O.G. 316-24 (Dec. 11, 1984).

It would clearly have been unnecessary for Congress to encourage the PTO to implement such an expansion of the law of double patenting if the doctrine already applied in situations where the statute applied. The inevitable implication of this 1984 development is that the doctrine of double patenting manifestly does *not* extend to those situations where Congress provides a statutory standard for separate patentability.

Thus, the Federal Circuit's decision is a sharp departure from the doctrine of double patenting as it has previously been understood. It is, in effect, the creation of a new doctrine that, irrationally and without any legal authority, overrules the results dictated by the patent statute.

C. Neither Laches nor Inequitable Conduct Has Been Alleged in This Case.

As explained above, the patent statute makes clear that Lilly is entitled to two separate patents for the two distinct inventions at issue in this case. The panel's evident concern that the Molloy patent would give Lilly an "unjustified timewise extension" does not justify the panel in overriding the statutorily mandated result that Lilly is entitled to two patents instead of one. Rather, the appropriate legal analysis for the panel's concern is rooted in a claim of laches or inequitable conduct –

namely, that Lilly unreasonably and unlawfully delayed the issuance of the basic Molloy patent.

Indeed, this was precisely the construct framed by then-Judge Taft when confronted with the identical issue over 100 years ago. As noted earlier, *supra* I, A, in *Ohio Brass*, as in this case, the defendant argued that the patent on the plaintiff's basic invention should be void because it issued after the patent claiming a later-discovered improvement on that basic invention. Judge Taft rejected this argument, reasoning in part that an inverted order of issuance has no legal consequence unless it is brought about deliberately:

> [I]t is said [by defendant] that if, by some chance, the application for the fundamental patent is delayed in its course through the patent office until a patent on the avowed improvement has issued, then the patent on the fundamental invention is void. In cases where the delay in the issuing of the patent for the main invention cannot be charged to the laches or fraud of the patentee, such a rule would be a hard one.

Ohio Brass, 80 F. at 724 (6th Cir. 1897) (Taft, J.). Thus, absent laches or fraud, Judge Taft held that "a patent for an improvement may expire before the patent for the main invention." *Id.* at 728.

The legal doctrines of laches and fraud, however, have never been invoked or argued in this case, and the evidence before the district court simply does not support a conclusion that Lilly unreasonably delayed its prosecution of the Molloy patent. Common law notions of laches require at a minimum an unreasonable and inexcusable delay, not just the possibility that action could have been taken sooner. *See A.C. Aukerman Co. v. R.L. Chaides Constr.*

Co., 960 F.2d 1020, 1024 (Fed. Cir. 1992). Here, the evidence shows that Lilly's prosecution of the Molloy patent was entirely reasonable and customary.[8]

Moreover, Respondents raised no such laches defense in the trial court, and they established no record for evaluating the reasonableness of Lilly's conduct in procuring the Molloy patent under a laches standard. Indeed, the record does not even include the full prosecution history of the Molloy patent. Laches simply cannot be raised for the first time on appeal, and certainly cannot fairly be permitted to lurk behind the panel's stated rationale as the disguised basis for stripping Lilly of a property right worth billions of dollars. To the contrary, if the panel was driven to its result by a concern that Lilly unjustifiably delayed its prosecution of the Molloy patent, then not only did it employ the wrong legal analysis and invoke the wrong legal doctrine, but it also manifestly denied Lilly its basic due process right to rebut that concern in an evidentiary proceeding.

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[8] To be sure, the panel did state in a footnote that the claims in the Molloy patent "could have been presented earlier" and that the PTO was not "*solely* responsible" for the long prosecution process, *see* App. 24a-25a & n.7 (emphasis added), but these vague statements hardly support a laches defense. Lilly's conduct here (identifying the need to present additional claims after completing prosecution of certain originally presented claims) is no different from that of the applicants in *In re Allen*, 343 F.2d 482 (C.C.P.A. 1965), and *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992), neither of which provoked judicial criticism.

D. The Decision Below Yields Absurd and Discriminatory Results.

Judge Newman closed her dissent from the Federal Circuit's refusal to hear this case *en banc* with the following plea: "In this period of unprecedented development of patent-supported biological advance, the nation needs a stable and comprehensible patent law, lest this court falter in its leading role in implementing the law's fundamental purpose." 251 F.3d at 976. Judge Newman's warnings that the panel's ruling was "truly anomalous" and that it "will surely add confusion and uncertainty to patent practice" were not heeded below. Accordingly, unless this Court vacates the decision below, a number of unhappy results will plague the nation's patent system.

1. The Decision Below Irrationally Discriminates Against Owners of Basic Patents.

The discriminatory effect of the rule of law announced by the Federal Circuit is apparent from the following hypothetical. Assume (1) Stark had been a scientist at Merck and the Stark patent was and is owned by Merck, (2) Lilly owned the Molloy patent, and (3) both patents were prosecuted exactly as they were by Lilly. Both patents would be enforceable for their full terms under the Federal Circuit opinion.

Assume further that a third party, such as Pfizer, subsequently acquires both patents. Does the policy that had permitted independent patent terms suddenly turn "about-face" and invalidate the patent on one of the patentably distinct inventions for "double patenting" just because ownership of the patents has changed? Judge Taft in *Ohio Brass* addressed and rejected precisely this proposition as a "reductio ad absurdum." *See* 80 F. 712, 727 (6th Cir. 1897).

Accordingly, like Pfizer in the foregoing example, Lilly should also be entitled to purchase the Stark patent

and similarly enjoy both patent terms. Moreover, this result cannot logically be different simply because Lilly acquired title to the Stark patent by virtue of *employing* Stark rather than *purchasing* the patent. But the Federal Circuit opinion holds otherwise: it says that *only* the owner of the original basic patent is prevented from obtaining a related improvement patent that issued before that basic patent issued. So viewed, the court's ruling is revealed to be both illogical and unjustifiably discriminatory against the owner of the basic patent. He alone is prohibited from enjoying the full terms of both patents.

2. The Decision Below Encourages Patentees To Manipulate the Patent System.

A second hypothetical reveals that the rule of law announced by the Federal Circuit cannot be justified by any countervailing benefit to the public. Assume the issue dates of the Stark and Molloy patents had been reversed, so that the Stark new-use patent issued seven months after, instead of seven months before, the Molloy basic patent. The public would be prohibited from using the Stark invention for precisely the same length of time – 17 years and seven months. Yet under the Federal Circuit's test there would be no "double patenting" because the later-issued Stark patent would not have been obvious from the earlier-issued Molloy patent. Thus, according to the Federal Circuit, the question of whether Lilly keeps both patents as valid and receives full patent protection for 17 years and seven months, or, instead, receives *zero* patent protection, depends not upon the level of harm suffered by the public but rather upon the happenstance of whether the Stark patent issues before, or after, the Molloy patent.

The Federal Circuit's decision undermines the very spirit of innovation that is the touchstone of patent law. If

the decision is allowed to stand, it will create a strong disincentive for further refinements of a new innovation until a patent has issued on the first invention. Surely, no inventor will run the risk of having the validity of its initial groundbreaking work nullified by the "premature" patenting of a subsequent improvement. As this case illustrates, there can be substantial delay in the issuance of a patent on a groundbreaking basic invention, and thus the Federal Circuit's disincentive for innovation will have a profound impact on innovation and patent prosecution. Patent owners will be compelled either not to seek improvement patents, or to delay their issuance until all of the basic patents have been secured.[9]

II. THE FEDERAL CIRCUIT ERRED IN PREEMPTIVELY DENYING LILLY THE STATUTORY RIGHT TO TERMINALLY DISCLAIM THE MOLLOY PATENT.

Even if the Federal Circuit were somehow correct, and Lilly's Stark and Molloy patents were properly considered "double patents," the decision nonetheless reaches a wholly irrational and erroneous result by holding Lilly's Molloy patent invalid in its entirety. That is not how the law of double patenting works. Indeed, that harsh result directly conflicts with the well-settled right of patentees, codified in Section 253 of the patent statute, to "terminally disclaim" their later-expiring patent in

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[9] In this regard, the rule of law announced by the Federal Circuit does nothing to remedy unwarranted prosecution delays, even though that was apparently its intended object. If Lilly had intentionally delayed issuance of the Stark patent 17 years after issuance of the Molloy patent, the public could not use the Stark invention for 34 years. Yet, there would be no "double patenting" under the Federal Circuit's decision because the Stark patent that issued second would be nonobvious from the Molloy patent that issued first.

order to preserve that portion of the patent that does not provide an unjustified timewise extension of patent exclusivity. *See* 35 U.S.C. § 253 ("[A]ny patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.").

The right to make a terminal disclaimer is the right to jettison that portion of the later-expiring "double patent" that has been held to provide an unjustified timewise extension because it extends beyond the expiration date of the earlier patent over which it has been held to be obvious. Such a disclaimer allows the patentee to preserve the remaining portion of the patent – the portion that does not extend beyond the statutory term of the earlier patent – as valid and enforceable. The terminal disclaimer effectively merges the claims of the "double patents" into a single patent enforceable for a single statutory term. *See In re Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967) (filing of a terminal disclaimer is "tantamount for all practical purposes to having all the claims in one patent"); *see also, e.g., Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 940 (Fed. Cir. 1992) ("[O]bviousness-type double patenting can be overcome by filing a terminal disclaimer."); *Quad Env't Tech. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 873 (Fed. Cir. 1991) ("Voluntary limitation of the term of the later-issued patent is a convenient response to an obvious-type double-patenting rejection."); *In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985) ("It is well-established that a common assignee is entitled to proceed with a terminal disclaimer to overcome a rejection based on double patenting of the obviousness type.") (citations omitted).

Thus, even if the Federal Circuit were correct in holding the Molloy basic patent to be an obvious double patent over the Stark new-use patent, Lilly is statutorily entitled to terminally disclaim that portion of the Molloy patent term extending beyond May 20, 2003, and thereby

to preserve the validity of the Molloy patent until that date. The property right thus preserved is worth approximately $4 billion.[10]

Nevertheless, in order to reach in its second opinion the same result it had improperly reached in its first opinion – the complete invalidity of the Molloy patent – the Federal Circuit held that Lilly was *not* entitled to file such a terminal disclaimer. *See* 251 F.3d at 968 n.5. The court's refusal to allow Lilly to file a terminal disclaimer not only contradicts Section 253 and uniform precedents applying it, the decision is also wholly irrational and unfair. In the panel's own words, the whole point of the "judicially-created doctrine of obviousness-type double patenting" is to "prohibit[ ] a party from obtaining an *extension* of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." App. 23a (emphasis added). Accordingly, the whole focus of a double-patenting case is on that portion of the later-expiring patent that *extends* beyond the expiration date of the earlier-expiring patent: that portion of the patent is the unjustified

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[10] While Respondents argued below that other Lilly patents could also be used to invalidate the Molloy patent for double patenting, these arguments were not accepted by the panel. For example, Respondents pointed to Lilly's new-use patents that was issued to Dr. Holland for the use of fluoxetine to treat high blood pressure. That patent cannot support a double patenting holding for all the reasons noted in Section I above with respect to the Stark patent. Moreover, it deals with peripheral effects of fluoxetine outside the brain and cannot, therefore, be linked to blockage of serotonin uptake in brain neurons as claimed in the Molloy patent, which likely explains why the Federal Circuit did not rely on it in its second opinion. Indeed, had the court been able to rely on the Holland patent, it would not have needed to distort the terminal disclaimer statute to reach its desired result because, unlike the Stark patent, the Holland patent is now expired.

timewise extension, and it is *that portion alone* that must be invalidated in order to fulfill the objectives of the doctrine of double patenting.

The Federal Circuit's sole rationale for this preemptive ruling was that Lilly had previously disclaimed all of the claims of the Stark patent in 1998. According to the court, Lilly "cannot now terminally disclaim the [Molloy] patent to expire at the same time the [Stark] patent would have expired had it not been disclaimed." App. 23a n.5.

This proposition, for which the court cited no authority, is self-evidently wrong. The disclaimer statute and the PTO rule implementing it, 37 C.F.R. § 1.321 (2001), impose no requirement that a first patent be maintained in force as a condition precedent to disclaiming a portion of the term of a second patent, nor has any case ever even hinted at this requirement. Moreover, it is utterly irrational and punitive to engraft such a requirement onto the statute. Since Section 253 allows a patentee to preserve the validity of his double patent by disclaiming *only* the portion of that patent extending beyond the statutory term of its earlier-issued twin, it cannot possibly be true that the patentee loses this right because he has *also* disclaimed *all* of the claims in the earlier-issued twin. In such a case, the patentee has, if anything, done more than Section 253 requires in order to preserve the double patent.

Finally, the panel's rationale for denying Lilly the right to use Section 253 underscores the harsh irony of this case. First, the panel ignored the fact that the Stark patent was legally and commercially irrelevant to Lilly, treating it as a robust patent whose statutory term Lilly could not be allowed to extend by the additional seven months contained in the later-issued Molloy patent. The panel then recognized that the Stark patent, having been disclaimed in its entirety, was illusory, and concluded that the Stark patent's illusory nature somehow prevented Lilly from enjoying *any exclusivity* from the Molloy patent, even *during* the Stark patent's original 17-year

term. In short, the panel cast the Stark patent in two irreconcilable roles – first as a robust patent whose term could not be extended through its purported Molloy twin, and then as a kind of "black hole" patent into whose void the Molloy patent vanished entirely.

CONCLUSION

The Federal Circuit in this case has improperly used the judge-made law of "double patenting" to override Congress in a case where the financial stakes could not be higher. More importantly, the decision below conflicts sharply with express provisions of the patent statute and with venerable precedent, and will have irrational and disruptive repercussions throughout the patent system.

For these and the foregoing reasons, it is respectfully requested that this petition for a writ of certiorari be granted.

Respectfully submitted,

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United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

DECIDED: May 30, 2001

ON PETITION FOR REHEARING EN BANC

Before MAYER, *Chief Judge*, FRIEDMAN, *Senior Circuit Judge*, and GAJARSA, *Circuit Judge*.

GAJARSA, *Circuit Judge*.

ORDER

On the petition for rehearing or rehearing *en banc*, the court accepted the petition for rehearing *en banc*. Acting

en banc, the court vacated the panel's original opinion entered on August 9, 2000, which is reported at 222 F.3d 973, 55 USPQ2d 1609 (Fed. Cir. 2000). The *en banc* court reassigned the opinion to the panel for a specific revision of the double patenting section. Based on the conclusions of the panel, the panel's original judgment affirming the district court's determination on the issue of best mode is reaffirmed. The panel's original judgment, which reversed the district court's determination that claim 7 of U.S. Patent No. 4,626,549 ("the '549 patent") is not invalid for double patenting, is reaffirmed, but on a different legal basis.

In December 1995, Barr Laboratories, Inc. ("Barr") filed an Abbreviated New Drug Application ("ANDA") under the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994), seeking approval from the Food and Drug Administration ("FDA") to market fluoxetine hydrochloride as an antidepressant. Fluoxetine hydrochloride is the active ingredient in Eli Lilly and Company's ("Lilly's") antidepressant drug Prozac. Lilly, on April 10, 1996, pursuant to 35 U.S.C. § 271(e)(2)(A) (1994), brought an infringement action in the United States District Court for the Southern District of Indiana, alleging that Barr's ANDA application infringed claim 5 of U.S. Patent No. 4,314,081 ("the '081 patent") and claim 7 the '549 patent. Lilly subsequently brought infringement actions against Geneva Pharmaceuticals, Inc., Apotex, Inc., and Bernard C. Sherman, all of whom had also filed ANDA applications with the FDA, and the actions were consolidated.

Barr and the other defendants (collectively "Barr") argued, *inter alia*, that claim 5 of the '081 patent and claim 7 of the '549 patent are invalid for failure to comply with

the best mode requirement and that claim 7 of the '549 patent is invalid for double patenting. On cross-motions for summary judgment, the district court held in favor of Lilly, concluding that neither claim violates the best mode requirement and that no double patenting exists.[1] Barr appeals the district court's summary judgment rulings, and Lilly cross-appeals the district court's ruling that Barr was entitled to a jury trial on its invalidity counterclaims. Because we hold that both claims comply with the best mode requirement but that claim 7 of the '549 patent is invalid for obviousness-type double patenting, we affirm-in-part and reverse-in-part. Accordingly, we also vacate the district court's ruling that Barr is entitled to a jury trial because we dispose of the validity issues on appeal.

I. BACKGROUND

The present appeal concerns the validity of claim 5 of the '081 patent, which covers the pharmaceutical compound fluoxetine hydrochloride – the active ingredient in Lilly's antidepressant drug Prozac – and claim 7 of the '549 patent, which covers the administration of fluoxetine hydrochloride to inhibit serotonin uptake in an animal's brain neurons.

On January 10, 1974, Lilly filed application Serial No. 432,379 ("the '379 application") containing claims for a class of compounds, therapeutic methods of using those

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[1] All other issues relating to validity were resolved by consent of the parties. As a result, the district court's judgment disposed of all claims at issue.

compounds, and pharmaceutical compositions comprising those compounds. The '379 application named Bryan B. Molloy ("Molloy") and Klaus K. Schmiegel as inventors. After its filing, the '379 application engendered a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy. When the last patent stemming from the '379 application issued in December 1986, the application had spawned four divisional applications, three continuation applications, and six patents. During that twelve-year period, Lilly obtained six patents relating to fluoxetine hydrochloride – the '081 and '549 patents, as well as U.S. Patent Nos. 4,018,895 ("the '895 patent"), 4,194,009 ("the '009 patent"), 4,590,213 ("the '213 patent"), and 4,329,356 ("the '356 patent"). The '213 and '356 patents did not stem from the '379 application, and during the course of this litigation, Lilly disclaimed those patents.

The '009 patent, which expired in April 1994, claimed a class of pharmaceutical compounds, including fluoxetine hydrochloride, for administration in pyschotropically effective amounts. The '895, '213, and '356 patents related to methods for treating particular ailments by administering a pharmaceutical compound within a class of compounds that includes fluoxetine hydrochloride. Specifically, the '895 patent, which expired in April 1994, concerned the treatment of humans suffering from depression; the '213 patent concerned the treatment of humans suffering from anxiety; and the '356 patent concerned the treatment of animals suffering from hypertension.

In December 1995, pursuant to a Paragraph IV certification under the Hatch Waxman Act, *see* 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV),[2] Barr filed an ANDA application seeking FDA approval to market fluoxetine hydrochloride as an antidepressant. Lilly responded by bringing an action in district court under 35 U.S.C. § 271(e)(2)(A),[3] asserting that Barr's ANDA application infringed claim 7 of the '549 patent and claim 5 of the '081 patent.

At the district court, Barr argued that both claims are invalid for failure to comply with the best mode requirement and that claim 7 of the '549 patent is invalid for obviousness-type double patenting. With regard to the best mode issue, Barr advanced two independent arguments. First, Barr argued that the claims are invalid because the patents failed to disclose Molloy's preferred method for synthesizing p-trifluoromethylphenol – a starting material necessary to make fluoxetine hydrochloride. Second, Barr argued that the claims are invalid because the patents failed to disclose Molloy's preferred solvent

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[2] This section provides, in pertinent part, as follows:

> An abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . for which the applicant is seeking approval under this subsection . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

35 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994).

[3] This section provides, in pertinent part, that "[i]t shall be an act of infringement to submit . . . an application under . . . [the Hatch-Waxman Act] . . . for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A).

for recrystallizing fluoxetine hydrochloride. With regard to the issue of double patenting, Barr advanced three independent arguments, contending that claim 7 of the '549 patent is invalid in light of (1) the '356 and '213 patents, (2) the '895 and '009 patents, and (3) the '081 patent.

On cross motions for summary judgment, the district court held in favor of Lilly, concluding that claim 5 of the '081 patent and claim 7 of the '549 patent do not violate the best mode requirement and that claim 7 is not invalid for double patenting under any of Barr's theories. The district court recognized that Barr contended that claim 7 of the '549 patent is invalid for double patenting over, *inter alia*, the '213 patent because it merely sets forth the "scientific explanation" for the subject matter of that and other Lilly patents. Yet, the district court determined that Barr failed to provide any authoritative, reliable scientific opinion to establish that claim 7 of the '549 patent constitutes merely the scientific explanation of what was already claimed in the patents that came before it, including the '213 patent.

This appeal followed. Because these issues concern disparate parts of the record evidence, we describe separately the background relevant to each argument.

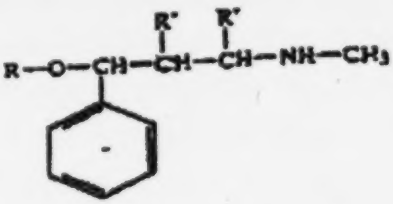
The Claims at Issue

A. Claim 5 of the '081 patent

Stemming directly from the '379 application, the '081 patent issued on February 2, 1982. Claim 5 of the '081

patent, which depends from claim 1, covers the compound N-methyl 3-(p-trifluoromethylphenoxy)-3-phenylpropylamine hydrochloride – commonly referred to as fluoxetine hydrochloride – and pharmaceutically-acceptable acid addition salts thereof formed with non-toxic acids. Claim 1, in turn, provides as follows:

A compound of the formula



wherein each R' is independently H or CH sub3 and R is m- or p-chlorophenyl, o-, m-, or p-methoxyphenyl, phenyl, o- or m-fluorophenyl, o- or p-tolyl, 2,4-difluorophenyl or p-trifluoromethylphenyl and acid addition salts formed with pharmaceutically-acceptable acids.

B. Claim 7 of the '549 patent

On March 31, 1986, Lilly filed continuation-in-part application Serial No. 846,448, claiming the benefit of the 1974 filing date of the '379 application under 35 U.S.C. § 120.[4] On December 2, 1986, the application matured into the '549 patent. Claim 7 of the '549 patent, which depends

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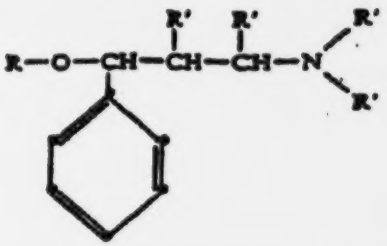
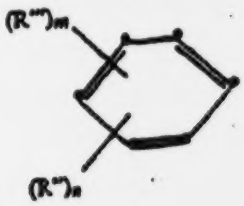
[4] Application Serial No. 846,448 was a continuation-in-part of Serial No. 544,654 (October 24, 1983), which was a continuation of Serial No. 872,147 (January 25, 1978), which in turn was a divisional of Serial No. 432,379 (January 10, 1974).

on claim 4, relates to blocking the uptake of the monoamine serotonin in an animal's brain neurons through administration of the compound N-methyl-3- (p-trifluoromethylphenoxy)-3-phenylpropylamine hydrochloride – commonly referred to as fluoxetine hydrochloride. Claim 4 provides as follows:

> A method of blocking the uptake of monoamines by brain neurons in animals comprising administering to said animal a monoamine blocking amount of a compound of the formula



> wherein each R' is independently hydrogen or methyl; wherein R is naphthyl or



> wherein R" and R' " are halo, trifluoromethyl, C sub1 -C sub4 alkyl, C sub1 -C sub3 alkyloxy or C sub3 -C sub4 alkenyl; and wherein n and m are 0, 1 or 2; and acid addition salts thereof formed with pharmaceutically-acceptable acids.

C. Best Mode: p-trifluoromethylphenol

Both the '081 and '549 patents identify p-trifluoromethylphenol as a starting material for making fluoxetine hydrochloride. During the early stages of experimentation, Molloy used commercial p-trifluoromethylphenol purchased from Marshallton Research Laboratories. However, when large quantities of p-trifluoromethylphenol were necessary for clinical testing, Lilly's division director refused to purchase p-trifluoromethylphenol due to the high costs. Instead, he required that Molloy and his colleagues synthesize their own p-trifluoromethylphenol.

To that end, Molloy worked with Lilly scientist Edward Lavagnino ("Lavagnino") to devise a cost-efficient method of synthesizing p-trifluoromethylphenol. After experimenting with various prior art methods, Molloy concluded that those methods were inadequate for generating a sufficient amount of p-trifluoromethylphenol for use in clinical testing. Then, following further research, Molloy and Lavagnino developed their own method for preparing p-trifluoromethylphenol that, as Lavagnino described in his deposition, was "superior" because it used "real cheap" starting material "available [in] tank car quantities." Also, in an article written after the filing of the '379 application, Molloy described his new synthesizing method as an improvement over prior art, because the "literature methods for [p-trifluoromethylphenol's] preparation are cumbersome and not easily adapted to large scale operations."

The '081 and '549 patents do not claim the material p-trifluoromethylphenol or a method for synthesizing it, nor do they disclose Molloy's method for synthesizing it.

D. Best Mode: Recrystallization

While experimenting with compounds claimed in the '081 and '549 patents, Molloy recrystallized the compounds in order to remove impurities and enhance their suitability for pharmaceutical use. The recrystallization process involved using a solvent to dissolve a sample of the compound and then separating the desired product in crystalline form from the impurities that remained dissolved. Between February 1973 and January 1974, Molloy and other Lilly scientists experimented with various solvents for recrystallizing fluoxetine hydrochloride and eventually found a particular solvent that produced a higher yield and higher purity than other solvents.

The record evidence illustrates that while Lilly scientists knew that some solvents for recrystallizing fluoxetine hydrochloride were more effective than others, choosing a suitable recrystallization solvent was well known to one of ordinary skill in the art. In particular, Dr. Elias J. Corey ("Corey"), a Nobel laureate, testified that fluoxetine hydrochloride is "generally quite easy to purify by recrystallizaton." Corey also explained that, although it requires some experimentation, selecting a recrystallization solvent is "very straightforward." Further, Barr's expert testified that "in 1974, sometimes the recrystallization of amine hydrochlorides was indeed routine."

The '081 and '549 patents do not claim a process for recrystallizing fluoxetine hydrochloride nor do they disclose any solvents for use in the recrystallizing fluoxetine hydrochloride.

E. Double Patenting: The '213 patent

On May 20, 1986, the '213 patent issued from an application filed on April 8, 1983. Claim 1 of the '213 patent provides:

> A method for treating anxiety in a human subject in need of such treatment which comprises the administration to such human an effective amount of fluoxetine or norfluoxetine or pharmaceutically acceptable salts thereof.

II. STANDARD OF REVIEW

We review a district court's grant of summary judgment *de novo*. *Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed. Cir. 1994). Summary judgment is appropriate when, based on the record, no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable jury could find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.2d 978, 980, 41 USPQ2d 1440, 1442 (Fed. Cir. 1997). A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *Anderson*, 477 U.S. at 248; *General Mills*, 103 F.2d at 980, 41 USPQ2d at 1442.

When evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits. *Anderson*, 477 U.S. at 252-53. Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through clear and convincing evidence, *see United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1563, 41 USPQ2d 1225, 1232 (Fed. Cir. 1997). Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise. Alternatively, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent. In determining whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the nonmoving party and resolves all doubts in its favor. *Anderson*, 477 U.S. at 255; *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274, 35 USPQ2d 1035, 1038 (Fed. Cir. 1995).

III. BEST MODE

Pursuant to § 112, ¶ 1, a patent specification must set forth the "best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, ¶ 1 (1994). The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge

of the preferred embodiments for practicing the claimed invention. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1532, 3 USPQ2d 1737, 1742 (Fed. Cir. 1987) (quoting *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962)).

Our case law explicating the best mode requirement focuses on a two-prong inquiry. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036-37 (Fed. Cir. 1990). First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1548, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997); *United States Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212, 37 USPQ2d 1388, 1390 (Fed. Cir. 1996). Second, if the inventor possessed a best mode, the factfinder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it. *Fonar*, 107 F.3d at 1548, 41 USPQ2d at 1804; *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390. The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time of filing. *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036. The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036-37.

With respect to the second prong of the best mode requirement, the extent of information that an inventor must disclose depends on the scope of the claimed invention. *Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20

USPQ2d 1300, 1302 (Fed. Cir. 1991). Accordingly, an inventor need not disclose a mode for obtaining unclaimed subject matter unless the subject matter is novel and essential for carrying out the best mode of the invention. *Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998). Furthermore, the best mode requirement does not extend to production details or routine details. *Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1143, 42 USPQ2d 1589, 1594-95 (Fed. Cir. 1997). Production details, which do not concern the "quality or nature of the [claimed] invention," *see id.* at 1143, 42 USPQ2d at 1595, relate to commercial and manufacturing considerations such as equipment on hand, certain available materials, prior relationships with suppliers, expected volume of production, and costs, *see Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1581, 21 USPQ2d 1123, 1128 (Fed. Cir. 1991) (explaining that a "step or source or technique considered 'best' in a manufacturing circumstance may have been selected for a non-'best mode' reason"). Routine details, on the other hand, implicate the quality and nature of invention, but their disclosure is unnecessary because they are readily apparent to one of ordinary skill in the art. *Young Dental*, 112 F.3d at 1143, 42 USPQ2d at 1595.

At the district court, Barr advanced two independent reasons for invalidating the '081 and '549 patents for failure to disclose the best mode: (1) Lilly failed to disclose Molloy's preferred method for synthesizing p-trifluoromethylphenol, and (2) it failed to disclose Molloy's

preferred solvent for recrystallizing the fluoxetine hydrochloride compound. On cross-motions for summary judgment, the district court held in favor of Lilly. Barr appeals, and we address each argument in turn.

A. Synthesizing p-trifluoromethylphenol

Barr contends that claim 5 of the '081 patent and claim 7 of the '549 patent do not meet the best mode requirement because the patents fail to disclose Molloy's method for synthesizing p-trifluoromethylphenol. In the present case, even assuming that Molloy preferred his method for synthesizing p-trifluoromethylphenol to alternative means of obtaining the material, we hold that failure to disclose the synthesizing method does not contravene the best mode requirement.

We begin our analysis by examining the scope of the claimed inventions. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302 ("The best mode inquiry is directed to what the applicant regards as his invention, which in turn is measured by the claims."). Claim 5 of the '081 patent covers a formula for the compound fluoxetine hydrochloride, and claim 7 of the '549 patent covers a method for blocking the uptake of serotonin by brain neurons through administering a dosage of fluoxetine hydrochloride. Example 1 in both the '081 and '549 patents identifies the chemical p-trifluoromethylphenol as a starting material for making fluoxetine hydrochloride. Neither patent, however, claims p-trifluoromethylphenol itself or a method for synthesizing it. Thus, while the best mode for developing fluoxetine hydrochloride involves use of p-trifluoromethylphenol, the claimed inventions

do not cover p- trifluoromethylphenol and the patents do not accord Lilly the right to exclude others from practicing Molloy's method for synthesizing p-trifluoromethylphenol. As a result, the best mode requirement does not compel disclosure of Molloy's unclaimed method for synthesizing p-trifluoromethylphenol.

Furthermore, the circumstances here are different from those in *Dana Corp. v. IPC Ltd.*, 860 F.2d 415, 418, 8 USPQ2d 1692 (Fed. Cir. 1988), and *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 940-41, 15 USPQ2d 1321, 1328 (Fed. Cir. 1990), in which an inventor failed to disclose unclaimed subject matter that was necessary for carrying out the best mode of the invention. In the present case, Molloy disclosed his preference for using p-trifluoromethylphenol when making fluoxetine hydrochloride. What he did not disclose, nor was he required to do so, was the unclaimed method for synthesizing p-trifluoromethylphenol. *Cf. Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 590, 7 USPQ2d 1050, 1054 (Fed. Cir. 1988) (finding no violation of best mode requirement by concealment of a preferred cleaning fluid formula when the claimed invention "neither added nor claimed to add anything to the prior art respecting cleaning fluid").

To be sure, if the best mode for carrying out a claimed invention involves novel subject matter, then an inventor must disclose a method for obtaining that subject matter even if it is unclaimed. *Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998); *Wahl Instruments*, 950 F.2d at 1583-84, 21 USPQ2d at 1130. That, however, is not the case here. In the present case, the record insistently

demonstrates that p-trifluoromethylphenol was commercially available at the time Lilly filed its original application. The record includes a product catalog from Marshallton Research Laboratories, dated January 1973, offering to sell p-trifluoromethylphenol. The record also contains an expert witness report explaining that p-trifluoromethylphenol was commercially available before 1974 from Aldrich Chemical Company. Additionally, the record includes prior art references that describe methods for preparing p-trifluoromethylphenol.

Barr contends that *Clayton v. Akiba*, 214 USPQ 374, 1982 WL 50444 (Bd. Pat. App. 1982), supports its position that Lilly was obligated to disclose the method for synthesizing p-trifluoromethylphenol. We do not find that argument persuasive. *Clayton*, aside from being non-binding on this court, involves facts that are inapposite to the present case. In *Clayton*, the claimed invention was a chemical compound, and the Board found that the inventor violated the best mode requirement by failing to disclose his method for preparing a necessary intermediate compound. *See id.* at 380-81. The Board's reasoning, however, hinged on the fact that the intermediate compound was "*itself admittedly a novel compound* . . . and, thus, its preparation [was] part and parcel of 'carrying out' the invention." *Id.* at 381 (emphasis added). Here, by contrast, the chemical p-trifluoromethylphenol, as explained above, was commercially available and described in the prior art.

Barr also seizes upon portions of the record evidence in an effort to establish a best mode violation. For example, Barr relies on Lavagnino's deposition testimony

that Molloy's method for synthesizing p-trifluoromethylphenol used material "available in tank car quantities, real cheap chemical, and simple transformations." Barr also cites Lavagnino's statement explaining that Molloy's synthesizing method could be "scaled up" to produce large amounts of p-trifluoromethylphenol. Barr points to Molloy's own statement that "the relatively high cost" of p-trifluoromethylphenol "is a limiting factor in its use as a chemical intermediate," and that he preferred his synthesizing method because other methods were "cumbersome and not easily adapted to large scale operations." Finally, Barr relies on evidence that Lilly stopped purchasing p-trifluoromethylphenol after Molloy developed his synthesizing method.

Rather than establishing a best mode violation, this amalgam of evidence provides paradigmatic examples of production details that the law excepts from best mode disclosure. Indeed, this evidence relates to considerations of costs, volume, and available resources for manufacturing fluoxetine hydrochloride, all details that are superfluous to the best mode requirement. *See Wahl Instruments*, 950 F.2d at 1581-82, 21 USPQ2d at 1128-29 (holding no best mode violation for failure to disclose a method chosen for reasons of cost and volume). In short, the reasons for using Molloy's synthesizing method were not linked to the intrinsic quality of fluoxetine hydrochloride, which is the thrust of the best mode requirement.

B. Recrystallization Solvent

Barr also argues that claim 5 of the '081 patent and claim 7 of the '549 patent violate the best mode requirement because Molloy failed to disclose the particular recrystallization solvent that he used to purify fluoxetine hydrochloride. Even assuming that Molloy preferred a particular and specific recrystallization solvent to others, we hold that failure to disclose that solvent does not violate the best mode requirement.

Once again, we begin our analysis with the scope of the claimed invention. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302. Claim 5 of the '081 patent covers the compound fluoxetine hydrochloride, and claim 7 of the '549 patent covers a method for administering it. Both patents teach that the preferred embodiment of fluoxetine hydrochloride is achieved by purifying the compound through recrystallization. Based on the record, there is no genuine issue that one of ordinary skill in the art possessed the requisite knowledge to select a solvent for recrystallizing fluoxetine hydrochloride. Even Barr's expert testified that "in 1974, sometimes the recrystallization of amine hydrochlorides was indeed routine." Choosing a solvent for performing recrystallization, therefore, constitutes a routine detail that falls outside the ambit of the best mode disclosure. *See Young Dental*, 112 F.3d at 1144, 42 USPQ2d at 1595; *Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 ("It is well established that what is within the skill of the art need not be disclosed to satisfy the best mode requirement as long as that mode is described.").

Barr contends that, even if choosing a solvent for recrystallization is a routine detail, the best mode requirement compels Molloy to disclose the particular and specific solvent he used in the recrystallization process. In effect, Barr argues that Molloy was obligated to disclose not only the preferred embodiment of the claimed invention, but also the preferred solvent for the unclaimed recrystallization process. Stated at a higher level of generality, Barr asserts that a patentee must disclose a preferred mode for carrying out an unclaimed routine detail. That position, however, is in conflict with the scope of the claims at issue, our prior decisions, and the purpose undergirding the best mode requirement.

As we have often said, "[i]t is concealment of the best mode of practicing the *claimed invention* that § 112, ¶ 1 is designed to prohibit." *Chemcast*, 913 F.2d at 927, 16 USPQ2d at 1036 (emphasis added). Here, the patents disclose that the best mode of the claimed invention is fluoxetine hydrochloride that is purified through recrystallization. The patents, however, do not claim a process for purifying fluoxetine hydrochloride through recrystallization or a solvent for performing the recrystallization. Thus, failure to disclose a preferred solvent does not equate to a best mode violation because the patents simply do not claim a recrystallization process or a recrystallization solvent. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302 ("Unclaimed subject matter is not subject to the disclosure requirements of § 112; the reasons are pragmatic: the disclosure would be boundless and the pitfalls endless."); *cf. Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1288, 55 USPQ2d 1065, 1070 (Fed. Cir. 2000) (holding no best mode violation

when inventor did not disclose an unclaimed, preferred method for use of the claimed invention – thin-line etching – because the claim covered a general process of plasma etching and the patent described the best mode for carrying out that process).

Further, § 112 requires only "an adequate disclosure of the best mode." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1025-26 (Fed. Cir. 1991). It logically follows that a patentee's failure to disclose an unclaimed, preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention. Indeed, Barr and other companies are able to recrystallize fluoxetine hydrochloride by using solvents different from the one Molloy used. In addition, our cases hold that a patentee complies with § 112 even though some experimentation is necessary to practice the best mode. *See id.* (holding that best mode does not require a "guarantee that every aspect of the specification be precisely and universally reproducible"); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1579-80 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85, 231 USPQ 81, 94 (Fed. Cir. 1986). In *Hybritech*, for example, this court held that the patentee did not violate § 112, even though carrying out the best mode of the invention involved screening experiments that were laborious and time consuming, because screening methods were known in the art. 802 F.2d at 1384-85, 231 USPQ at 94. Similarly, in the present case, solvents for recrystallizing fluoxetine hydrochloride were known in

the art, and simply because selecting a desired solvent may have required some experimentation, nondisclosure of Molloy's particular solvent does not rise to a best mode violation.

Moreover, the purpose behind the best mode requirement supports our conclusion. As we explained in *Amgen*, the best mode requirement establishes a *quid pro quo* whereby the patentee "must not receive the right to exclude others unless at the time of filing he has provided an adequate disclosure of the best mode." 927 F.2d at 1210, 18 USPQ2d at 1024. The best mode requirement, however, is a two-way street, and in the present case, the '081 and '549 patents do not grant Lilly the right to exclude others from practicing Molloy's method of recrystallization or from using his preferred solvent. Thus, it would be incongruous to require that Molloy disclose that information nonetheless. *See Randomex*, 849 F.2d at 588, 7 USPQ2d at 1053 ("It is concealment of the best mode of practicing the *claimed invention* that section 112, ¶ 1 is designed to prohibit." (emphasis in original)).

In sum, because no genuine issue of material fact exists upon which a reasonable jury could find that claim 5 and claim 7 did not comply with the best mode requirement, we affirm the district court's grant of summary judgment in favor of Lilly. Thus, we have no occasion to determine if Barr has a right to a jury trial on that issue.

III. DOUBLE PATENTING

Through a statutorily prescribed term, Congress limits the duration of a patentee's right to exclude others from practicing a claimed invention. 35 U.S.C. § 154(a)(2)

(1994). The judicially-created doctrine of obviousness-type double patenting cements that legislative limitation by prohibiting a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent. *In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985) (explaining that, even though no explicit statutory basis exists for obviousness-type double patenting, the doctrine is necessary to prevent a patent term extension through claims in a second patent that are not patentably distinct from those in the first patent).[5] As one of our predecessor courts explained, "[t]he fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *In re Van Ornum*, 686 F.2d 937, 943-44, 214 USPQ 761, 766 (CCPA 1982) (quoting *In re Schneller*, 397 F.2d 350, 158 USPQ 210, 214 (CCPA 1968)).

Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in

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[5] A patent owner cannot avoid double patenting by disclaiming the earlier patent. Further, because Lilly disclaimed the '213 patent, it cannot now terminally disclaim the '549 patent to expire at the time the '213 patent would have expired had it not been disclaimed. That is, the fact that the '213 patent has been disclaimed is of no help to Lilly, as double patenting precludes claim 7 of the '549 patent from extending beyond the termination date of the '213 patent, whether that termination date is at the end of its normal term or, as in this case, is the date it is terminated via disclaimer.

the later patent and determines the differences.[6] *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326, 52 USPQ2d 1590, 1593 (Fed. Cir. 1999). Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. *Id.* at 1327, 52 USPQ2d at 1595. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. *In re Berg*, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998). A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim. *In re Longi*, 759 F.2d at 896, 225 USPQ at 651 (affirming a holding of obviousness-type double patenting because the claims at issue were obvious over claims in four prior art patents); *In re Berg*, 140 F.3d at 1437, 46 USPQ2d at 1233 (Fed. Cir. 1998) (affirming a holding of obviousness-type double patenting where a patent application claim to a genus is anticipated by a patent claim to a species within that genus).

On appeal, we limit our inquiry to an analysis of whether claim 7 of the '549 patent is invalid for obvious-type double patenting over claim 1 of the '213 patent.[7] In

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[6] An absence of overlap between the later claim and the earlier claim does not preclude a conclusion that the later claim is patentably indistinct from the earlier claim.

[7] A two-way double patenting test does not apply in this case. The two-way test is only appropriate in the unusual circumstance where, *inter alia*, the United States Patent and Trademark Office ("PTO") is "*solely* responsible for the delay in causing the second-filed application to issue prior to the first." (emphasis added). *In re Berg*, 140 F.3d at 1437, 46 USPQ2d at

accordance with the two-prong obviousness-type double patenting test demarcated in *Georgia-Pacific*, we first construe the claims at issue and determine the differences in subject matter between these two claims. The relevant portion of claim 1 of the '213 patent is directed to a method for treating anxiety in a human by administering an effective amount of fluoxetine or a pharmaceutically-acceptable salt thereof. '213 patent, col. 2, ll. 34-39. Claim 7 of the '549 patent covers a method of blocking the uptake of serotonin by brain neurons in animals by administering the compound fluoxetine hydrochloride. '549 patent, col. 20, ll. 7-9.

A person of ordinary skill in the art would have recognized that fluoxetine hydrochloride is a pharmaceutically-acceptable salt of fluoxetine. In fact, hydrochloride salts are the most common pharmaceutically acceptable salts of basic drugs, and hence are obvious compounds. *See, e.g., The Merck Index of Chemicals and*

1233 (Fed. Cir. 1998); *see also In re Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993) (holding that PTO actions did not dictate the rate of prosecution when Goodman accepted early issuance of species claims and filed a continuation application to prosecute genus claims). Such circumstances are not present in this case, because the PTO was not solely responsible for the delay. Indeed, the '549 patent issued in December 1986, approximately eight months after a continuation-in-part was filed, which stemmed from a continuation application, which in turn stemmed from a divisional of the original '379 application that was filed in January 1974. Further, an expert hired on behalf of Lilly in the matters of PTO and corporate intellectual property practice, in discussing claim 7 of the '549 patent, stated: "[I]t is true that the claim could have been presented earlier. . . . " This statement indicates that the delay was not solely caused by the PTO.

Drugs (Paul G. Stecher et al. eds., 7th ed. 1960) (listing multiple hydrochloride salts of drugs).

Therefore, the only difference between claim 1 of the '213 patent and claim 7 of the '549 patent is that the former addresses a method of treating anxiety in humans with fluoxetine hydrochloride while the latter claims a method of using fluoxetine hydrochloride to block serotonin uptake in animals. Having recognized the difference between the claims at issue, we must decide whether this difference renders the claims patentably distinct.

Serotonin uptake inhibition is a natural biological activity that occurs when fluoxetine hydrochloride is administered to an animal, such as a human, for any purpose, including the treatment of anxiety. That is, serotonin uptake inhibition is an inherent property of fluoxetine hydrochloride upon its administration. Barr has offered a panoply of evidence to support the recognition of this inherent biological function of fluoxetine hydrochloride.

In Lilly's March 24, 1998 10-K filing with the Securities and Exchange Commission, Lilly pointed out that serotonin uptake inhibition is the "process by which Prozac works." The title of a 1995 article published by Lilly also indicates that Prozac is a serotonin uptake inhibitor: *Minireview Prozac (Fluoxetine, Lilly 110140), The First Selective Serotonin Uptake Inhibitor and Antidepressant Drug: Twenty Years Since Its First Publication.*[8] David T. Wong,

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[8] The reference to "selective" means that fluoxetine hydrochloride inhibits the uptake of serotonin to a greater

Frank P. Bymaster, & Eric A. Engleman, at 1 (1995). The summary of this article "describe[s] the evolutionary process involved in the discovery of the selective 5-HT [serotonin] uptake inhibitor, fluoxetine. . . . "[9] *Id.* at 1. The first full sentence of the article states: "Fluoxetine (Prozac) first appeared in scientific literature as Lilly 110140 (the hydrochloride form), a selective serotonin uptake inhibitor, in the August 15, 1974 issue of *Life Sciences.*" *Id.* The article continues: "After twenty-plus years of extensive investigations, inhibition of serotonin uptake remains the major mechanism of action for fluoxetine. . . . " *Id.* Several tables in the article specifically demarcate amounts of serotonin uptake inhibition resulting from fluoxetine administration. *Id.* at 7, 10-12, 14, 18. The article even illustrates chemical structures of several serotonin uptake inhibitors, one of which is fluoxetine. *Id.* at 9. The article concludes by stating that despite "intensive investigation," including over 5500 research papers on the subject, fluoxetine "is still regarded as a selective [serotonin] uptake inhibitor."

During a deposition, Lilly's expert, Alan Frazer, divulged that "[t]here is no doubt in my mind" that fluoxetine hydrochloride inhibits serotonin reuptake in "the vast majority" of people that ingest fluoxetine hydrochloride. Frazer also stated that he had "no doubt" that inhibition reuptake in brain neurons is the expected consequence of administering fluoxetine hydrochloide. Frazer further acknowledged in a sworn statement that:

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degree than it inhibits the uptake of other monoamines (such as dopamine or norepinephrine).

[9] The Wong article defines 5-HT as serotonin. Wong at 2.

"Clearly, there are [sic] a wealth of data demonstrating that the uptake of serotonin is inhibited in most humans when fluoxetine is administered." Another one of Lilly's experts, Louis Lemberger, stated in the course of a deposition: "If you give fluoxetine hydrochloride to a human being you are going to inhibit serotonin uptake. . . . " Yet another Lilly expert, Irwin Slater, also agreed that ingesting fluoxetine hydrochloride will result in the inhibition of serotonin uptake in brain neurons.

Likewise, Barr's expert, Fridolin Sulser, stated in an affidavit that "[t]he pharmalogical effect of administering fluoxetine hydrochloride is to inhibit serotonin reuptake in brain neurons." He also recognized that "it is literally impossible to treat someone for anxiety . . . with fluoxetine hydrochloride without at the same time inhibiting serotonin reuptake." In an expert report, Dr. Sulser again reiterated that "the primary pharmalogical effect of fluoxetine is the inhibition of serotonin reuptake in brain neurons." He further reiterated that administering fluoxetine hydrochloride "will inherently and inevitably block the reuptake of serotonin. . . . " He provided a wealth of support for these opinions. Another Barr expert, Robert Roth, also stated that "[t]he biological activity of claim 7 of the '549 patent[ ] inherently and inevitably occurs whenever someone practices . . . the '213 . . . patent[ ]." He continued, stating that "there is no doubt" that "administration of fluoxetine hydrochloride inherently and inevitably blocks the reuptake of serotonin. . . . " Dr. Roth provided a plethora of support for his opinion.

Lilly has not proffered any significant evidence rebutting Barr's ample foundation for the proposition

that administration of fluoxetine hydrochloride naturally and inherently inhibits the uptake of serotonin.

A reference is anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1346, 51 USPQ2d 1943, 1945 (Fed. Cir. 1999). A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (citations omitted). In this case, it is clear from all of the evidence proffered by Barr that the natural result flowing from administration of fluoxetine hydrochloride is inhibition of serotonin uptake. Therefore, the limitation of claim 7 of the '549 patent directed to blocking serotonin uptake by use of fluoxetine hydrochloride is an inherent characteristic of the administration of fluoxetine hydrochloride for any purpose, including the treatment of anxiety.

A patentable distinction does not lie where a later claim is anticipated by an earlier one. That is, a later patent claim that fails to provide novel invention over an earlier claim is not patentably distinct from the earlier claim. Salient aspects of the case at issue are factually similar to *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 32 USPQ2d 1915 (Fed. Cir. 1994). That case involved several patents directed to the use of 3'-azidothymidine ("AZT") to treat individuals infected with the human immunodeficiency virus ("HIV") or individuals who had acquired immunodeficiency syndrome ("AIDS"), and involved United States Patent No. 4,818,750 ("the '750 patent"), which covered a method of

using AZT to increase the T-lymphocyte count of persons infected with HIV. *Burroughs Wellcome*, 40 F.3d at 1225, 32 USPQ2d at 1916-17. While never directly addressed by the majority, in his partial dissent, Judge Lourie articulated that the '750 patent should have been invalidated for double patenting because the method claimed in the '750 patent "is an inherent, inevitable result of the practice of the other method patents claiming treatment of HIV or AIDS." *Id.* at 1233, 32 USPQ2d at 1924 (Lourie, J., dissenting-in-part). He stated that because the method claimed in the '750 patent was inherent in the use of AZT to treat HIV and AIDS patients, it lacked novelty. *Id.* He continued, suggesting that allowing a common owner to receive both a patent claiming the physical act of treating individuals that have HIV or AIDS and a patent covering the result that such treatment accomplishes makes "no sense." *Id.* at 1234, 32 USPQ2d at 1924. "It amounts to deciding that treating a person in pain with aspirin is one invention and invoking the pain relieving mechanism by means of that treatment is another." *Id.*

Similarly, in the case at bar, claim 7 of the '549 patent simply describes the process by which fluoxetine hydrochloride physically acts on individuals who receive the drug. That is, fluoxetine hydrochloride inherently blocks serotonin uptake upon administration. Therefore, no patentable distinction rests between administering fluoxetine hydrochloride for treatment of anxiety and inhibition of serotonin uptake by administration of fluoxetine hydrochloride.

The only other difference between claim 1 of the '213 patent and claim 7 of the '549 patent is that the former is directed to humans while the latter is directed to animals.

Humans are a species of the animal genus. Our case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim. *In re Berg*, 140 F.3d at 1437, 46 USPQ2d at 1233 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993); *In re Gosteli*, 872 F.2d 1008, 1010, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d at 944, 214 USPQ at 767 (C.C.P.A. 1982).

A motion for summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists if there is sufficient evidence for a jury to return a verdict in favor of the nonmoving party on the particular issue. *Anderson*, 477 U.S. at 248. While the burden rests on the party moving for summary judgment to show "that there is an absence of evidence to support the non-moving party's case," the nonmoving party must affirmatively demonstrate by specific factual allegations that a genuine issue of material fact exists for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 325. In this case, Barr moved for summary judgment that claim 7 of the '549 patent was invalid for double patenting over, *inter alia*, claim 1 of the '213 patent. Barr has presented an abundance of evidence indicating that the natural result of fluoxetine hydrochloride is the inhibition of serotonin uptake. Lilly has not proffered sufficient evidence in response to this evidence. Therefore, there remains no

genuine issue of fact as to this issue. That is, there is not sufficient evidence on which a jury could base a finding that fluoxetine hydrochloride does not inhibit the uptake of serotonin. Accordingly, the district court erred by indicating that Barr failed to establish that inhibition of serotonin uptake merely describes a biological result of fluoxetine hydrochloride administration for the treatment of anxiety. Further, there is no issue of fact as to whether a human is a species of the animal genus or whether fluoxetine hydrochloride is a pharmaceutically-acceptable salt of fluoxetine. Consequently, the double patenting issue in this case is solely a matter of law.

We have compared the differences between the claims at issue as a whole and conclude that they are not patentably distinct. Therefore, we reverse the district court's denial of the portion of Barr's motion for summary judgment contending that claim 7 of the '549 patent is invalid for obviousness-type double patenting over claim 1 of the '213 patent. Consequently, the portion of Barr's motion for summary judgment pertaining to double patenting is granted. The district court's grant of Lilly's motion for summary judgment pertaining to double patenting is reversed.

IV. CONCLUSION

Because we hold that claim 5 of the '081 patent and claim 7 of the '549 patent comply with the best mode requirement and that claim 7 is invalid for obviousness-type double patenting in view of claim 1 of the '213 patent, we affirm-in-part and reverse-in-part. Further,

because we do not reach the issue, we vacate the district court's grant of a jury trial to Barr.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND VACATED.

COSTS

Each party shall bear its own costs.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiff-cross appellant, Eli Lilly and Company. With him on the brief were *Allen M. Sokal, Kenneth M. Frankel,* and *David S. Forman.* Of counsel was *L. Scott Burwell.* Of counsel on the brief were *Douglas K. Norman,* and *James P. Leeds,* Eli Lilly and Company, of Indianapolis, Indiana.

Richard S. Clark, Rochelle K. Seide, Marta E. Delsignore, Louis Sorell, Robert Neuner, and *Thomas J. Parker,* Baker & Botts, of New York, New York, for defendant-appellant, Geneva Pharmaceuticals, Inc.

George C. Lombardi, Winston & Strawn, of Chicago, Illinois, argued for defendant-appellant Barr Laboratories, Inc. With him on the brief were *James F. Hurst, Dan K. Webb, Bradley C. Graveline, Christine J. Siwik*, and *Taras A. Gracey*. Of counsel on the brief was Mark E. Waddell, Bryan Cave, LLP, of New York, New York. Of counsel was *Derek John Sarafa*.

Hugh L. Moore, and *Diane I. Jennings*, Lord, Bissell & Brook, of Chicago, Illinois for defendants-appellants Apotex, Inc. and Bernard C. Sherman.

Jeffrey P. Kushan, Powell, Goldstein, Frazer & Murphy LLP, of Washington, DC, for amicus curiae Biotechnology Industry Organization. Of counsel on the brief were *Richard Medway* and *Eric M. Solovy*, Powell, Goldstein, Frazer & Murphy LLP; and *Charles E. Ludlam*, Biotechnology Industry Organization, of Washington, DC.

William L. Mentlik, Lerner, David, Littenberg, Krumholz & Mentlik, LLP, of Westfield, New Jersey, for amicus curiae Zenith Goldline Pharmaceuticals, Inc.

Joseph P. Lavelle, Howrey Simon Arnold & White, of Washington, DC, for amicus curiae Intellectual Property Owners Association.

John C. Vassil, Morgan & Finnegan, L.L.P., of New York, New York, for amicus curiae Federal Circuit Bar Association. With him on the brief were *Michael P. Dougherty, Tony V. Pezzano*, and *Tini Thomas*. Of counsel on the brief were *George E. Hutchinson* and *Philip C. Swain*, Federal Circuit Bar Association, of Washington, DC.

Janice M. Mueller, Associate Professor, The John Marshall Law School, of Chicago, Illinois, amicus curiae.

Nancy J. Linck, Guilford Pharmaceuticals Inc., of Baltimore, Maryland, for amicus curiae Guilford Pharmaceuticals Inc.

Appealed from: United States District Court for the Southern District of Indiana

Chief Judge Sara Evans Barker

United States Court of Appeals for the Federal Circuit

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ORDER

Eli Lilly and Company filed a combined petition for panel rehearing and rehearing en banc. Responses thereto were invited by the court, and filed by Geneva Pharmaceuticals, Inc., and Barr Laboratories, Inc. The petition for rehearing and responses[1] were referred to the panel

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[1] Amicus curiae briefs were filed by:

a- Intellectual Property Owners Association
b- Federal Circuit Bar Association
c- Professor Janice M. Mueller
d- Guilford Pharmaceuticals Inc.

that heard the appeal, and thereafter, referred to the circuit judges who are in regular active service.

Acting *en banc*, the court accepted the petition for rehearing en banc, and vacated the panel's opinion entered on August 9, 2000, which is reported at 222 F.3d 973 (Fed. Cir. 2000). The en banc court reassigned the appeals to the panel, which issues a separate opinion today.

Circuit Judge Newman dissents in a separate opinion.

Circuit Judge Linn did not participate in the vote.

FOR THE COURT,

MAY 30 2001
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

MAY 30 2001

JAN HORBALY
CLERK

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e- Biotechnology Industry Organization
f- Zenith Goldline Pharmaceuticals, Inc.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

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Chief Judge Sarah Evans Barker

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99-1262, -1263, -1264, -1303

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Defendants-Appellants,

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INTERPHARM, INC.,

Defendant.

NEWMAN, *Circuit Judge,* dissenting from the refusal to reconsider the case *en banc.*

The Federal Circuit, sitting *en banc,* vacated the panel's prior opinion issued on August 9, 2000 and returned the case to the panel for further consideration. The panel now again holds claim 7 of the '549 (Molloy) patent invalid for double patenting, but this time it bases that determination on a different patent, the '213 patent (Stark). The panel now grants summary judgment invalidating claim 7 of the '549 patent for double patenting with the Stark patent. However, this shift has led the panel into factual and legal areas that were not developed at trial, and into misapplication and misstatement of the law of double patenting. I must, respectfully, dissent.

Obviousness-Type Double Patenting

The judge made law of obviousness-type double patenting was developed to cover the situation where patents are not citable as a reference against each other and therefore can not be examined for compliance with the rule that only one patent is available per invention. Double patenting thus is applied when neither patent is prior art against the other, usually because they have a common priority date. *See General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278-81, 23 USPQ2d 1839, 1843-46 (Fed.Cir.1992) (summarizing the criteria for obviousness-type double patenting). As the court explained in *In re Boylan*, 392 F.2d 1017, 1018 n.1, 157 USPQ 370, 371 n.1 (CCPA 1968), "it must always be carefully observed that the appellant's patent is not 'prior art' under either section 102 or section 103 of the 1952 Patent Act."

These fundamental requirements for application of the law of double patenting are not met by the '549 and Stark patents. The Stark patent was filed nine years after the effective filing date of the '549 patent; there is no formal relationship between them; the '549 disclosure was a cited reference against Stark; and they have different inventorships. The panel ignores these routine criteria and the effect they have on a double patenting analysis. Whatever effect the '549 and Stark patents may have on each other, it is not "double patenting."

The district court had rejected Barr's double patenting arguments after summary judgment proceedings, ruling that:

> Barr's primary contention is that claim 7 of the '549 patent is invalid for double patenting because it merely sets forth the "scientific explanation" for the subject matter of certain of Lilly's other patents. Barr's summary judgment briefing on this issue is a confusing amalgamation of broad patent law principles that are not clearly applicable to the issues before the Court. In fact, the only case law cited in support of its theory is a dissenting opinion, never adopted thereafter by any court as best we could determine. Even disregarding any limitation on the application of this legal theory to the issues at hand, we observe that Barr's briefs focus extensively on the formulation and restatement of its legal theory to the exclusion of any evidence sufficient to explain or support it. Most notably, Barr has failed to provide any authoritative, reliable scientific opinion to establish that claim 7 of the '549 patent constitutes merely the later scientific explanation of what has already been claimed in the patents that came before.

On presumably the same record, the panel now grants summary judgment and *sua sponte* finds double patenting between claim 7 of the '549 patent and claim 1 of the Stark patent. The '549 disclosure, in the form of three issued divisional patents, was prior art cited against the Stark patent. Patentability of the Stark claims over this prior art was successfully argued in the PTO. The panel reaches the anomalous conclusion that the earlier filed '549 patent (effective filing date January 10, 1974) is invalid for obviousness-type double patenting with the Stark patent that was filed nine years later (April 8, 1983). Such a result is not available under the laws of 35 U.S.C.

§102 and §103; neither can it be achieved under the rubric of double patenting.

The claims are:

Claim 7 of the '549 Molloy patent:

> The method of claim 4 [blocking the uptake of monoamines by brain neurons in animals] comprising administering to said animal a monoamine blocking amount of N-methyl-3-p-trifluoromethylphenoxy-3-phenylproplyamine [fluoxetine] or a pharmaceutically-acceptable acid addition salt thereof.

Claim 1 of the '213 Stark patent:

> A method for treating anxiety in a human subject in need of such treatment which comprises the administration to said human of an effective amount of fluoxetine or norfluoxetine or pharmaceutically-acceptable salts thereof.[1]

The panel holds that the later-discovered and later-filed anxiety-treatment use of fluoxetine invalidates the patent on the earlier discovery of monoamine (serotonin) blocking use because the earlier discovery is "inherent" in the later one. That is not a correct statement of either the law of double patenting or the law of inherency. The 1974 invention can not be invalidated based on what was filed and claimed in the 1983 application, even on the panel's incorrect view of the law of inherency as applied to biological inventions.

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[1] A biological property or new use of a composition is claimed as a "method of use," in accordance with 35 U.S.C. 101. Both claim 7 of the '549 patent and claim 1 of the Stark patent are method-of-use claims.

The district court remarked on the absence of reliable evidence as well as legal precedent to support Barr's proffered theories. The panel, however, finds that "Barr has offered a panoply of evidence to support the recognition of this inherent biological function." Panel op. at 23. I take note that the panel cites only references dated after the '549 application was filed. These references are not prior art to the '549 claims. Later discoveries and scientific advances may well elucidate the earlier ones, but that does not retrospectively erase the patentability of the earlier work.

The complex factual issues that have been raised in the record, in connection with the relationship between serotonin uptake and the various pharmaceutical uses of fluoxetine, can not be resolved in favor of Barr and adversely to Lilly on the summary judgment record, for the material facts have been placed squarely at issue. Indeed, the scientific evidence in the record weighs heavily against the panel's findings.

It is highly relevant that the Stark application was examined in light of prior art that included the '549 Molloy disclosure. While Barr cites cases that established rules with respect to the subsequent patentability of a genus when a species is known, this has no relevance to the question at bar. Further, these rules relate to whether a subsequent invention is patentable, not a prior one. Here, however, it is the first-filed (Molloy) invention that the panel invalidates in view of the later-filed Stark invention. Although the Stark patent issued seven months before the '549 patent, the panel incorrectly holds that the later-filed but earlier-issued Stark claim renders

obvious the '549 claim of nine years earlier priority. Neither *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir.1998), relied on by the panel, nor any other case, supports such an inverted holding.

When two patents issue with claims that are not patentably distinct, the principle served by the judge made law of double patenting is that because patent protection started with the first patent to issue, it should not extend to the expiration of the second patent to issue. Thus the law of double patenting does not consider the patents as prior art; the law simply requires elimination of the extension of exclusivity by truncating the term of the second patent to issue, to coincide with the term of the first patent to issue.

When the second patent to issue is (as here) the first patent that was filed, an anomaly may arise when there is a valid charge of obviousness-type double patenting. I repeat, that charge is not here available because the first patent that was filed was in fact a reference against the second patent. The panel, ignoring this immutable fact, undertakes an obviousness-type double patenting analysis. When two patents are appropriately considered for obviousness-type double patenting, an anomaly arises, for example, when the claims of patent B are "obvious" in light of the claims of patent A, but the claims of patent A are not obvious in light of the claims of patent B. An illustration is shown in In re Berg, where one patent was directed to a species, and the other to a genus that included the species. A genus is usually not patentable over a species, but a species may, depending on the facts, be patentable over the genus. Judge made law has developed a special and simple test for double patenting in

such a situation: the requirement of "cross-reading." By applying the rules of cross-reading, double patenting will not lie, for cases in which the first patent to issue is the second patent that was filed, unless the claims cross read; that is, unless the claims of each patent would have been obvious in view of the claims of the other patent. This simple expedient avoids the analytical trap into which the panel fell.

The panel has reached the truly anomalous result of holding invalid for obviousness, on a theory of obviousness-type double patenting, an invention that was made and applied for nine years before the asserted "prior art" was filed.

The panel states that *In re Berg* requires that unless the PTO is solely and exclusively responsible for all delays in issuing the first-filed patent, the patentee can not rely on the fact of its earlier filing. That is not the *Berg* holding. In *Berg* the same inventors filed, on the same day, patent applications whose claims stood in the relationship of genus and species of the same method for preparing an abrasive particle suitable for use in an abrasive composition. When the species application was about to issue, the examiner rejected the genus application on the grounds of obviousness-type double patenting. Berg argued that each application should be evaluated as to whether it represented a patentable advance over the other, a two-way test of cross-reading applied in particular circumstances. This court stated that the purpose of the two-way test, as it had been developed in our precedent, was "to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but,

through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing." The Federal Circuit then held that Berg was not entitled to the benefits of the two-way test because he could have included all of the claims in a single application. Neither the facts of Berg nor the law as developed therein applies to the patents here under consideration.

The panel also holds that because Lilly disclaimed the Stark patent before trial, this bars Lilly from disclaiming that portion of the '549 patent that would have extended beyond the Stark patent's original life. No precedent so holds, and I discern no basis for such a new rule. A terminal disclaimer is a standard response to a charge of double patenting; this remedy need not be withheld, at least in the absence of fraud or bad faith. To deny a patentee the opportunity of simplifying the issues or improving its litigation position is an unnecessary if not a punitive action, unwarranted on this record.

The New Rules of Patentability of Biological Inventions

The panel states that "the natural result of fluoxetine hydrochloride is the inhibition of serotonin uptake," and holds that a discovery of a new and unobvious biological property is unpatentable because it is inherent in the chemical compound. As authority the panel cites a dissenting opinion in *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1233, 32 USPQ2d 1915, 1924 (Fed.Cir.1994) (Lourie, J. dissenting in part), the dissent

suggesting that a patent to a method which "is an inherent, inevitable result of the practice" of another method patent constitutes same-invention double patenting. Thus the panel holds the '549 claim to serotonin inhibition to be invalid as the natural and inherent result of the Stark treatment for relief of anxiety. However, every biological property is a natural and inherent result of the chemical structure from which it arises, whether or not it has been discovered. To negate the patentability of a discovery of biological activity because it is "the natural result" of the chemical compound can have powerful consequences for the patentability of biological inventions. The narrow facts of *Burroughs Wellcome* and the dissenting view therein do not warrant the new rule now adopted.

The panel also states that "there is not sufficient evidence on which a jury could base a finding that fluoxetine hydrochloride does not inhibit the uptake of serotonin." Indeed, it is far from clear what could be proved, as well as what must be proved, on the panel's theory of double patenting, for the many scientific articles cited in the record show the complexity of the mechanism of action of fluoxetine. However, the panel's ruling that Lilly would have to prove that serotonin inhibition does not occur on treatment with fluoxetine, in order to avoid double patenting invalidity of its claim for serotonin inhibition on treatment with fluoxetine, will surely add confusion and uncertainty to patent practice.

In this period of unprecedented development of patent-supported biological advance, the nation needs a stable and comprehensible patent law, lest this court falter in its leading role in implementing the law's fundamental purposes.

NOTE: Pursuant to Fed. Cir. R. 47.6 this order is not citable as precedent. It is a public order.

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BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ON MOTION

Before MAYER, *Chief Judge*, FRIEDMAN, *Senior Circuit Judge*, and GAJARSA, *Circuit Judge*.

ORDER

The Biotechnology Industry Organization (BIO) moves for leave to file, and to set a time to file, an amicus curiae brief in support of Eli Lilly and Company's (Lilly) combined petition for rehearing and rehearing en banc.

BIO states that Lilly consents to this motion, while the Appellants do not consent.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The motion is denied.

FOR THE COURT,

JUN 15 2001
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Richard S. Clark, Esq.
James F. Hurst, Esq.
Hugh L. Moore, Esq.
Joseph P. Lavelle, Esq.
William L. Mentlik, Esq.
John C. Vassil, Esq.
Janice M. Mueller, Esq.
Nancy J. Linck, Esq.
Jeffrey P. Kushan, Esq.

FILED
U.S. COURT
OF APPEALS FOR
THE FEDERAL CIRCUIT
JUN 15 2001
JAN HORBALY
CLERK

NOTE: Pursuant to Fed. Cir. R. 47.6 this order is not citable as precedent. It is a public order.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ON MOTION

Before MAYER, *Chief Judge*, NEWMAN, MICHEL, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, and DYK, *Circuit Judges*.

ORDER

The Biotechnology Industry Organization ("BIO") moves for en banc reconsideration, joined by the Pharmaceutical Research and Manufacturers of America, the National Association of Manufacturers, and the Federal

Circuit Bar Association, of the panel's June 15, 2001, order denying BIO leave to file, and to set a time to file, an amicus curiae brief in support of Eli Lilly and Company's combined petition for rehearing and rehearing en banc.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.

NEWMAN, LOURIE, RADER, and DYK, *Circuit Judges*, would allow the brief to be filed. LINN, *Circuit Judge*, did not participate in the vote.

FOR THE COURT,

JUN 27 2001
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Richard S. Clark, Esq.
James F. Hurst, Esq.
Hugh L. Moore, Esq.
Herbert C. Warnsley, Esq.
William L. Mentlik, Esq.
John C. Vassil, Esq.
Janice M. Mueller, Esq.
Nancy J. Linck, Esq.
Jeffrey P. Kushan, Esq.

FILED
U.S. COURT
OF APPEALS FOR
THE FEDERAL CIRCUIT
JUN 27 2001
JAN HORBALY
CLERK

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United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ON MOTION

Before MAYER, *Chief Judge*, NEWMAN, MICHEL, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, and DYK, *Circuit Judges*.

ORDER

The Intellectual Property Owners Association ("IPO") moves for leave to file an amicus curiae brief in support of Eli Lilly and Company's combined petition for rehearing and rehearing en banc. IPO indicates that Barr

Laboratories, Inc. has not consented to the filing of this amicus brief.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.

NEWMAN, LOURIE, RADER, and DYK, *Circuit Judges*, would allow the brief to be filed. LINN, *Circuit Judge*, did not participate in the vote.

FOR THE COURT,

JUN 27 2001
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Richard S. Clark, Esq.
James F. Hurst, Esq.
Hugh L. Moore, Esq.
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FILED
U.S. COURT
OF APPEALS FOR
THE FEDERAL CIRCUIT
JUN 27 2001
JAN HORBALY
CLERK

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

DECIDED: August 9, 2000

Before MAYER, *Circuit Judge*, FRIEDMAN, *Senior Circuit Judge*, and GAJARSA, *Circuit Judge*.

GAJARSA, *Circuit Judge*.

Barr Laboratories, Inc. ("Barr"), in December 1995, filed an Abbreviated New Drug Application ("ANDA") under the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994), seeking approval from the Food and Drug Administration ("FDA") to market fluoxetine hydrochloride as an antidepressant. Fluoxetine hydrochloride is the active ingredient in Eli Lilly and

Company's ("Lilly's") antidepressant drug Prozac. Lilly, on April 10, 1996, pursuant to 35 U.S.C. § 271(e)(2)(A) (1994), brought an infringement action in the United States District Court for the Southern District of Indiana, alleging that Barr's ANDA application infringed claim 5 of U.S. Patent No. 4,314,081 ("the '081 patent") and claim 7 of U.S. Patent No. 4,626,549 ("the '549 patent"). Lilly subsequently brought infringement actions against Geneva Pharmaceuticals, Inc., Apotex, Inc., and Bernard C. Sherman, all of whom had also filed ANDA applications with the FDA, and the actions were consolidated.

Barr and the other defendants (collectively "Barr") argued, *inter alia,* that claim 5 of the '081 patent and claim 7 of the '549 patent are invalid for failure to comply with the best mode requirement and that claim 7 of the '549 patent is invalid for double patenting. On cross-motions for summary judgment, the district court held in favor of Lilly, concluding that neither claim violates the best mode requirement and that no double patenting exists.[1] Barr appeals the district court's summary judgment rulings, and Lilly cross-appeals the district court's ruling that Barr was entitled to a jury trial on its invalidity counterclaims. Because we hold that both claims comply with the best mode requirement but that claim 7 of the '549 patent is invalid for obviousness-type double patenting, we affirm-in-part and reverse-in-part. Accordingly, we also vacate the district court's ruling that Barr is entitled to a

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[1] All other issues relating to validity were resolved by consent of the parties. As a result, the district court's judgment disposed of all claims at issue.

jury trial because we dispose of the validity issues on appeal.

I. BACKGROUND

The present appeal concerns the validity of claim 5 of the '081 patent that covers the pharmaceutical compound fluoxetine hydrochloride – the active ingredient in Lilly's antidepressant drug Prozac – and claim 7 of the '549 patent that covers the administration of fluoxetine hydrochloride to inhibit serotonin uptake in an animal's brain neurons.

On January 10, 1974, Lilly filed application Serial No. 432,379 ("the '379 application") containing claims for a class of compounds, therapeutic methods of using those compounds, and pharmaceutical compositions comprising those compounds. The '379 application named Bryan B. Molloy ("Molloy") and Klaus K. Schmiegel as inventors. After its filing, the '379 application engendered a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy. When the last patent stemming from the '379 application issued in December 1986, the application had spawned four divisional applications, three continuation applications, and six patents. During that twelve-year period, Lilly obtained six patents relating to fluoxetine hydrochloride – the '081 and '549 patents, as well as U.S. Patent Nos. 4,018,895 ("the '895 patent"), 4,194,009 ("the '009 patent"), 4,590,213 ("the '213 patent"), and 4,329,356 ("the '356 patent"). The '213 and '356 patents did not stem from the '379 application, and during the course of this litigation, Lilly disclaimed those patents.

The '009 patent, which expired in April 1994, claimed a class of pharmaceutical compounds, including fluoxetine hydrochloride, for administration in pyschotropically effective amounts. The '895, '213, and '356 patents related to methods for treating particular ailments by administering a pharmaceutical compound within a class of compounds that includes fluoxetine hydrochloride. Specifically, the '895 patent, which expired in April 1994, concerned the treatment of humans suffering from depression; the '213 patent concerned the treatment of humans suffering from anxiety; and the '356 patent concerned the treatment of animals suffering from hypertension.

In December 1995, pursuant to a Paragraph IV certification under the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994),[2] Barr filed an ANDA application seeking FDA approval to market fluoxetine hydrochloride as an antidepressant. Lilly responded by bringing an action in district court under 35 U.S.C.

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[2] This section provides, in pertinent part, as follows:

> An abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . for which the applicant is seeking approval under this subsection . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

35 U.S.C. § 355(j)(2)(A)(vii)(IV).

§ 271(e)(2)(A) (1994),[3] asserting that Barr's ANDA application infringed claim 7 of the '549 patent and claim 5 of the '081 patent.

At the district court, Barr argued that both claims are invalid for failure to comply with the best mode requirement and that claim 7 of the '549 patent is invalid for obviousness-type double patenting. With regard to the issue of best mode, Barr advanced two independent arguments. First, Barr argued that the claims are invalid because the patents failed to disclose Molloy's preferred method for synthesizing p-trifluoromethylphenol – a starting material necessary to make fluoxetine hydrochloride. Second, Barr argued that the claims are invalid because the patents failed to disclose Molloy's preferred solvent for recrystallizing fluoxetine hydrochloride. With regard to the issue of double patenting, Barr advanced three independent arguments, contending that claim 7 of the '549 patent is invalid in light of (1) the '356 and '213 patents, (2) the '895 and '009 patents, and (3) the '081 patent.

On cross motions for summary judgment, the district court held in favor of Lilly, concluding that claim 5 of the '081 patent and claim 7 of the '549 patent do not violate the best mode requirement and that claim 7 is not invalid for double patenting under any of Barr's theories. This appeal followed. Because these issues concern disparate

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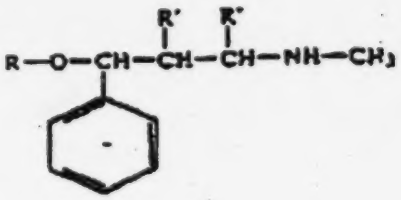
[3] This section provides, in pertinent part, that "[i]t shall be an act of infringement to submit . . . an application under . . . [the Hatch-Waxman Act] . . . for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A).

parts of the record evidence, we describe separately the background relevant to each argument.

The Claims at Issue

A. Claim 5 of the '081 patent

Stemming directly from the '379 application, the '081 patent issued on February 2, 1982. Claim 5 of the '081 patent, which depends on claim 1, covers the compound N-methyl 3-(p-trifluoromethylphenoxy)-3-phenylpropylamine hydrochloride – commonly referred to as fluoxetine hydrochloride – and pharmaceutically-acceptable acid addition salts thereof formed with non-toxic acids. Claim 1, in turn, provides as follows:

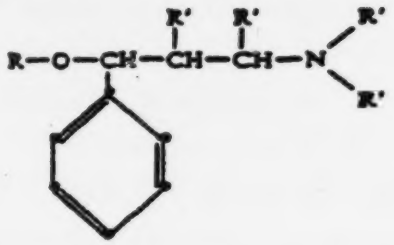
> A compound of the formula
>
> 
>
> wherein each R' is independently H or CH_3 and R is m- or p-chlorophenyl, o-, m-, or p-methoxyphenyl, phenyl, o- or m-fluorophenyl, o- or p-tolyl, 2,4-difluorophenyl or p-trifluoromethylphenyl and acid addition salts formed with pharmaceutically-acceptable acids.

B. Claim 7 of the '549 patent

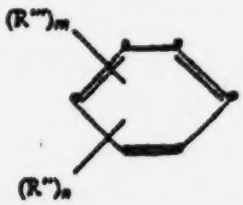
On March 31, 1986, Lilly filed continuation application Serial No. 846,448, claiming the benefit of the 1974 filing date of the '379 application under 35 U.S.C. § 120.

On December 2, 1986, the application matured into the 549 patent. Claim 7 of the '549 patent, which depends on claim 4, relates to blocking the uptake of the monoamine serotonin in an animal's brain neurons through administration of the compound N-methyl-3-(p-trifluoromethylphenoxy)-3-phenylpropylamine hydrochloride – commonly referred to as fluoxetine hydrochloride. Claim 4 provides as follows:

> A method of blocking the uptake of monoamines by brain neurons in animals comprising administering to said animal a monoamine blocking amount of a compound of the formula



wherein each R' is independently hydrogen or methyl; wherein R is naphthyl or



wherein R" and R'" are halo, trifluoromethyl, C_1-C_4 alkyl, C_1-C_3 alkyloxy or C_3-C_4 alkenyl; and wherein n and m are 0, 1 or 2; and acid addition salts thereof formed with pharmaceutically-acceptable acids.

C. Best Mode: p-trifluoromethylphenol

Both the '081 and '549 patents identify p-trifluoromethylphenol as a starting material for making fluoxetine hydrochloride. During the early stages of experimentation, Molloy used commercial p-trifluoromethylphenol purchased from Marshallton Research Laboratories. However, when large quantities of p-trifluoromethylphenol were necessary for clinical testing, Lilly's division director refused to purchase p-trifluoromethylphenol due to the high costs. Instead, he required that Molloy and his colleagues synthesize their own p-trifluoromethylphenol.

To that end, Molloy worked with Lilly scientist Edward Lavagnino ("Lavagnino") to devise a cost efficient method of synthesizing p-trifluoromethylphenol. After experimenting with various prior art methods, Molloy concluded that those methods were inadequate for generating a sufficient amount of p-trifluoromethylphenol for use in clinical testing. Then, following further research, Molloy and Lavagnino developed their own method for preparing p-trifluoromethylphenol that, as Lavagnino described in his deposition, was "superior" because it used "real cheap" starting material "available [in] tank car quantities." Also, in an article written after the filing of the '379 application, Molloy described his new synthesizing method as an improvement over prior art, because the "literature methods for [p-trifluoromethylphenol's] preparation are cumbersome and not easily adapted to large scale operations."

The '081 and '549 patents do not claim the material p-trifluoromethylphenol or a method for synthesizing it, nor do they disclose Molloy's method for synthesizing it.

D. Best Mode: Recrystallization

While experimenting with compounds claimed in the '081 and '549 patents, Molloy recrystallized the compounds in order to remove impurities and enhance their suitability for pharmaceutical use. The recrystallization process involved using a solvent to dissolve a sample of the compound and then separating the desired product in crystalline form from the impurities that remained dissolved. Between February 1973 and January 1974, Molloy and other Lilly scientists experimented with various solvents for recrystallizing fluoxetine hydrochloride and eventually found a particular solvent that produced a higher yield and higher purity than other solvents.

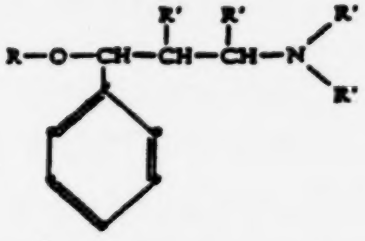
The record evidence illustrates that while Lilly scientists knew that some solvents for recrystallizing fluoxetine hydrochloride were more effective than others, choosing a suitable recrystallization solvent was well known to one of ordinary skill in the art. In particular, Dr. Elias J. Corey ("Corey"), a Nobel laureate, testified that fluoxetine hydrochloride is "generally quite easy to purify by recrystallizaton." Corey also explained that, although it requires some experimentation, selecting a recrystallization solvent is "very straightforward." Further, Barr's expert testified that "in 1974, sometimes the recrystallization of amine hydrochlorides was indeed routine."

The '081 and '549 patents do not claim a process for recrystallizing fluoxetine hydrochloride nor do they disclose any solvents for use in the recrystallizing fluoxetine hydrochloride.

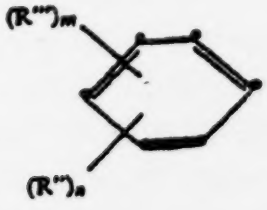
E. Double Patenting: The '895 patent

On March 4, 1977, divisional application Serial No. 514,094 matured into the '895 patent. Claim 1 of the '895 patent, the only independent claim, provides as follows:

> A method of treating human suffering from depression which comprises administering to said human an effective antidepressant dose of a compound of the formula:



> wherein each R' is independently hydrogen or methyl; wherein R is naphthyl or



> wherein R" and R"' are halo, trifluoromethyl, C_1-C_4 alkyl, C_1-C_3 alkyloxy or C_3-C_4 alkenyl; and wherein n and m are 0, 1 or 2; and acid addition

salts thereof formed with a pharmaceutically-acceptable acid.

Put differently, claim 1 of the '895 patent covers the administration of a pharmaceutical compound within a class of claimed compounds to treat depression in humans. The '895 patent expired in April 1994.

II. STANDARD OF REVIEW

We review a district court's grant of summary judgment *de novo*. *See Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 U.S.P.Q.2d 1373, 1377 (Fed. Cir. 1994). Summary judgment is appropriate when, based on the record, no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable jury could find for the nonmoving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.2d 978, 980, 41 U.S.P.Q.2d 1440, 1442 (Fed. Cir. 1997). A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *See Anderson*, 477 U.S. at 248; *General Mills*, 103 F.2d at 980, 41 U.S.P.Q.2d at 1442.

When evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits. *See Anderson*, 477 U.S. at 252-53. Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282 (1994), which can be overcome only through clear and convincing evidence, *see United*

States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1563, 41 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1997). Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise. Alternatively, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent. In determining whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the nonmoving party and resolves all doubts in its favor. *See Anderson*, 477 U.S. at 255; *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274, 35 U.S.P.Q.2d 1035, 1038 (Fed. Cir. 1995).

III. BEST MODE

Pursuant to section 112, ¶ 1, a patent specification must set forth the "best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, ¶ 1 (1994). The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1532, 3 USPQ2d 1737, 1742 (Fed. Cir. 1987) (quoting *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962)).

Our case law explicating the best mode requirement focuses on a two-prong inquiry. *See Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036-37 (Fed. Cir. 1990). First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. *See Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1548, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997); *United States Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212, 37 USPQ2d 1388, 1390 (Fed. Cir. 1996). Second, if the inventor possessed a best mode, the factfinder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it. *See Fonar*, 107 F.3d at 1548, 41 USPQ2d at 1804; *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390. The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time of filing. *See U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036. The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *See U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036-37.

With respect to the second prong of the best mode requirement, the extent of information that an inventor must disclose depends on the scope of the claimed invention. *See Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20 USPQ2d 1300, 1302 (Fed. Cir. 1991). Accordingly, an inventor need not disclose a mode for obtaining unclaimed subject matter unless the subject matter is novel and essential for carrying out the best mode of the invention. *See Applied Med. Resources Corp. v. United States*

Surgical Corp., 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998). Furthermore, the best mode requirement does not extend to production details or routine details. *See Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1143, 42 USPQ2d 1589, 1594-95 (Fed. Cir. 1997). Production details, which do not concern the "quality or nature of the [claimed] invention," *see id.* at 1143, 42 USPQ2d at 1595, relate to commercial and manufacturing considerations such as equipment on hand, certain available materials, prior relationships with suppliers, expected volume of production, and costs, *see Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1581, 21 USPQ2d 1123, 1128 (Fed. Cir. 1991) (explaining that a "step or source or technique considered 'best' in a manufacturing circumstance may have been selected for a non-'best mode' reason"). Routine details, on the other hand, implicate the quality and nature of invention, but their disclosure is unnecessary because they are readily apparent to one of ordinary skill in the art. *See Young Dental*, 112 F.3d at 1143, 42 USPQ2d at 1595.

At the district court, Barr advanced two independent reasons for invalidating the '081 and '549 patents for failure to disclose the best mode: (1) Lilly failed to disclose Molloy's preferred method for synthesizing p-trifluoromethylphenol, and (2) it failed to disclose Molloy's preferred solvent for recrystallizing the fluoxetine hydrochloride compound. On cross motions for summary judgment, the district court held in favor of Lilly. Barr appeals, and we address each argument in turn.

A. Synthesizing p-trifluoromethylphenol

Barr contends that claim 5 of the '081 patent and claim 7 of the '549 patent do not meet the best mode requirement because the patents fail to disclose Molloy's method for synthesizing p-trifluoromethylphenol. In the present case, even assuming that Molloy preferred his method for synthesizing p-trifluoromethylphenol to alternative means of obtaining the material, we hold that failure to disclose the synthesizing method does not contravene the best mode requirement.

We begin our analysis by examining the scope of the claimed inventions. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302 ("The best mode inquiry is directed to what the applicant regards as his invention, which in turn is measured by the claims."). Claim 5 of the '081 patent covers a formula for the compound fluoxetine hydrochloride, and claim 7 of the '549 patent covers a method for blocking the uptake of serotonin by brain neurons through administering a dosage of fluoxetine hydrochloride. Example 1 in both the '081 and '549 patents identifies the chemical p-trifluoromethylphenol as a starting material for making fluoxetine hydrochloride. Neither patent, however, claims p-trifluoromethylphenol itself or a method for synthesizing it. Thus, while the best mode for developing fluoxetine hydrochloride involves use of p-trifluoromethylphenol, the claimed inventions do not cover p-trifluoromethylphenol and the patents do not accord Lilly the right to exclude others from practicing Molloy's method for synthesizing p-trifluoromethylphenol. As a result, the best mode requirement does not compel disclosure of Molloy's

unclaimed method for synthesizing p-trifluoromethylphenol.

Furthermore, the circumstances here are different from those in *Dana Corp. v. IPC Ltd., Partnership*, 860 F.2d 415, 418, 8 USPQ2d 1692 (Fed. Cir. 1988), and *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 940-41, 15 USPQ2d 1321, 1328 (Fed. Cir. 1990), in which an inventor failed to disclose unclaimed subject matter that was necessary for carrying out the best mode of the invention. In the present case, Molloy disclosed his preference for using p-trifluoromethylphenol when making fluoxetine hydrochloride. What he did not disclose, nor was he required to do so, was the unclaimed method for synthesizing p-trifluoromethylphenol. *Cf. Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 590, 7 USPQ2d 1050, 1054 (Fed. Cir. 1988) (finding no violation of best mode requirement by concealment of a preferred cleaning fluid formula when the claimed invention "neither added nor claimed to add anything to the prior art respecting cleaning fluid").

To be sure, if the best mode for carrying out a claimed invention involves novel subject matter, then an inventor must disclose a method for obtaining that subject matter even if it is unclaimed. *See Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998); *Wahl Instruments*, 950 F.2d at 1583-84, 21 USPQ2d at 1130. That, however, is not the case here. In the present case, the record insistently demonstrates that p-trifluoromethylphenol was commercially available at the time Lilly filed its original application. The record includes a product catalog from Marshallton Research

Laboratories, dated January 1973, offering to sell p-trifluoromethylphenol. The record also contains an expert witness report explaining that p-trifluoromethylphenol was commercially available before 1974 from Aldrich Chemical Company. Additionally, the record includes prior art references that describe methods for preparing p-trifluoromethylphenol.

Barr contends that *Clayton v. Akiba*, 214 USPQ 374 (Bd. Pat. App. 1982), supports its position that Lilly was obligated to disclose the method for synthesizing p-trifluoromethylphenol. We do not find that argument persuasive. *Clayton*, aside from being non-binding on this court, involves facts that are inapposite to the present case. In *Clayton*, the claimed invention was a chemical compound, and the Board found that the inventor violated the best mode requirement by failing to disclose his method for preparing a necessary intermediate compound. *See id.* at 380-81. The Board's reasoning, however, hinged on the fact that the intermediate compound was "*itself admittedly a novel compound* . . . and, thus, its preparation [was] part and parcel of 'carrying out' the invention." *Id.* at 381 (emphasis added). Here, by contrast, the chemical p-trifluoromethylphenol, as explained above, was commercially available and described in the prior art.

Barr also seizes upon portions of the record evidence in an effort to establish a best mode violation. For example, Barr relies on Lavagnino's deposition testimony that Molloy's method for synthesizing p-trifluoromethylphenol used material "available in tank car quantities, real cheap chemical, and simple transformations." Barr also cites Lavagnino's statement explaining

that Molloy's synthesizing method could be "scaled up" to produce large amounts of p-trifluoromethylphenol. Barr points to Molloy's own statement that "the relatively high cost" of p-trifluoromethylphenol "is a limiting factor in its use as a chemical intermediate," and that he preferred his synthesizing method because other methods were "cumbersome and not easily adapted to large scale operations." Finally, Barr relies on evidence that Lilly stopped purchasing p-trifluoromethylphenol after Molloy developed his synthesizing method.

Rather than establishing a best mode violation, this amalgam of evidence provides paradigmatic examples of production details that the law excepts from best mode disclosure. Indeed, this evidence relates to considerations of costs, volume, and available resources for manufacturing fluoxetine hydrochloride, all details that are superfluous to the best mode requirement. *See Wahl Instruments*, 950 F.2d at 1581-82, 21 USPQ2d 1128-29 (holding no best mode violation for failure to disclose a method chosen for reasons of cost and volume). In short, the reasons for using Molloy's synthesizing method were not linked to the intrinsic quality of fluoxetine hydrochloride, which is the thrust of the best mode requirement.

B. Recrystallization Solvent

Barr also argues that claim 5 of the '081 patent and claim 7 of the '549 patent violate the best mode requirement because Molloy failed to disclose the particular recrystallization solvent that he used to purify fluoxetine hydrochloride. Even assuming that Molloy preferred a

particular and specific recrystallization solvent to others, we hold that failure to disclose that solvent does not violate the best mode requirement.

Once again, we begin our analysis with the scope of the claimed invention. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302. Claim 5 of the '081 patent covers the compound fluoxetine hydrochloride, and claim 7 of the '549 patent covers a method for administering it. Both patents teach that the preferred embodiment of fluoxetine hydrochloride is achieved by purifying the compound through recrystallization. Based on the record, there is no genuine issue that one of ordinary skill in the art possessed the requisite knowledge to select a solvent for recrystallizing fluoxetine hydrochloride. Even Barr's expert testified that "in 1974, sometimes the recrystallization of amine hydrochlorides was indeed routine." Choosing a solvent for performing recrystallization, therefore, constitutes a routine detail that falls outside the ambit of the best mode disclosure. *See Young Dental*, 112 F.3d at 1144, 42 USPQ2d at 1595; *Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 ("It is well established that what is within the skill of the art need not be disclosed to satisfy the best mode requirement as long as that mode is described.").

Barr contends that, even if choosing a solvent for recrystallization is a routine detail, the best mode requirement compels Molloy to disclose the particular and specific solvent he used in the recrystallization process. In effect, Barr argues that Molloy was obligated to disclose not only the preferred embodiment of the claimed invention but also the preferred solvent for the unclaimed

recrystallization process. Stated at a higher level of generality, Barr asserts that a patentee must disclose a preferred mode for carrying out an unclaimed routine detail. That position, however, is in conflict with the scope of the claims at issue, our prior decisions, and the purpose undergirding the best mode requirement.

As we have often said, "[i]t is concealment of the best mode of practicing the *claimed invention* that section 112, ¶ 1 is designed to prohibit." *Chemcast*, 913 F.2d at 927, 16 USPQ2d at 1036 (emphasis added). Here, the patents disclose that the best mode of the claimed invention is fluoxetine hydrochloride that is purified through recrystallization. The patents, however, do not claim a process for purifying fluoxetine hydrochloride through recrystallization or a solvent for performing the recrystallization. Thus, failure to disclose a preferred solvent does not equate to a best mode violation because the patents simply do not claim a recrystallization process or a recrystallization solvent.

See Engel Indus., 946 F.2d at 1531, 20 USPQ2d at 1302 ("Unclaimed subject matter is not subject to the disclosure requirements of § 112; the reasons are pragmatic: the disclosure would be boundless and the pitfalls endless."); *cf. Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1288, 55 USPQ2d 1065, 1070 (Fed. Cir. 2000) (holding no best mode violation when inventor did not disclose an unclaimed, preferred method for use of the claimed invention – thin-line etching – because the claim covered a general process of plasma etching and the patent described the best mode for carrying out that process).

Further, section 112 requires only "an adequate disclosure of the best mode." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1025-26 (Fed. Cir. 1991). It logically follows that a patentee's failure to disclose an unclaimed, preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention. Indeed, here, Barr and other companies are able to recrystallize fluoxetine hydrochloride by using solvents different from the one Molloy used. In addition, our cases hold that a patentee complies with section 112 even though some experimentation is necessary to practice the best mode. *See id.* (holding that best mode does not require a "guarantee that every aspect of the specification be precisely and universally reproducible"); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1579-80 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85, 231 USPQ 81, 94 (Fed. Cir. 1986). In *Hybritech*, for example, this court held that the patentee did not violate section 112 even though carrying out the best mode of the invention involved screening experiments that were laborious and time consuming, because screening methods were known in the art. *See* 802 F.2d at 1384-85, 231 USPQ at 94. Similarly, in the present case, solvents for recrystallizing fluoxetine hydrochloride were known in the art, and simply because selecting a desired solvent may have required some experimentation, non-disclosure of Molloy's particular solvent does not rise to a best mode violation.

Moreover, the purpose behind the best mode requirement supports our conclusion. As we explained in *Amgen*, the best mode requirement establishes a *quid pro quo* whereby the patentee "must not receive the right to exclude others unless at the time of filing he has provided an adequate disclosure of the best mode." 927 F.2d at 1210, 18 USPQ2d at 1024. The best mode requirement, however, is a two-way street, and in the present case, the '081 and '549 patents do not grant Lilly the right to exclude others from practicing Molloy's method of recrystallization or from using his preferred solvent. Thus, it would be incongruous to require that Molloy disclose that information nonetheless. *See Randomex*, 849 F.2d at 588, 7 USPQ2d at 1053 ("It is concealment of the best mode of practicing the *claimed invention* that section 112, ¶ 1 is designed to prohibit." (emphasis in original)).

In sum, because no genuine issue of material fact exists upon which a reasonable jury could find that claim 5 and claim 7 did not comply with the best mode requirement, we affirm the district court's grant of summary judgment in favor of Lilly. Thus, we have no occasion to determine if Barr has a right to a jury trial on that issue.

III. DOUBLE PATENTING

Through a statutorily prescribed term, Congress limits the duration of a patentee's right to exclude others from practicing a claimed invention. *See* 35 U.S.C. § 154(a)(2) (Supp. 1998) (discussing the length of a patent term). The judicially-created doctrine of obviousness-type double patenting cements that legislative limitation by

prohibiting a party from obtaining an extension of exclusive rights through claims in a later patent that are not patentably distinct from claims in an earlier patent. *See In re Braat*, 937 F.2d 589, 592, 19 USPQ2d 1289, 1291-92 (Fed. Cir. 1991); *In re Longi*. 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985) (explaining that, even though no explicit statutory basis exists for obviousness-type double patenting, the doctrine is necessary to prevent a patent term extension through claims in a second patent that are not patentably distinct from those in the first patent). As our predecessor court explained, "[t]he fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *In re Van Ornum*, 686 F.2d 937, 943-44, 214 USPQ 761, 766 (CCPA 1982) (quoting *In re Schneller*, 397 F.2d 350, 158 USPQ 210, 214 (1968)).[4]

Obviousness-type double patenting entails a two-step analysis. First, as a matter of law, the court construes the claim in the earlier patent and the claim in the later patent, and it overlays the later claim on the earlier claim to determine whether the later claim encompasses subject matter previously claimed.[5] *See Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326, 52 USPQ2d

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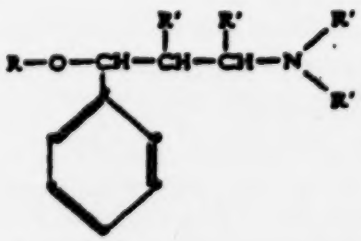
[4] A patentee can cure invalidity for double patenting by filing a terminal disclaimer, thereby foregoing the portion of the term of the later patent that extends beyond the term of the earlier patent. In the present case, however, Lilly did not file a terminal disclaimer with respect to claim 7 of the '549 patent.

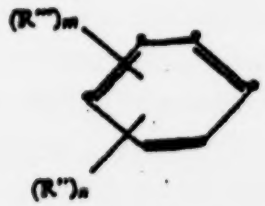
[5] An absence of overlap between the later claim and the earlier claim does not preclude a conclusion that the later claim is patentably indistinct from the earlier claim.

1590, 1593 (Fed. Cir. 1999) (stating that "analysis of the claims is the first step" in an obviousness-type double patenting inquiry); *General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1844 (Fed. Cir. 1992). Second, the court determines whether the differences in subject matter between the two claims is such that the claims are patentably distinct. *See Georgia-Pacific*, 195 F.3d at 1327, 52 USPQ2d at 1595 (proceeding to determine whether differences between the two claims are patentably distinct after construing the claims); *General Foods*, 972 F.2d at 1279, 23 USPQ2d at 1844 (explaining that the terms "patentably distinguishable," "patentable distinctions," and obvious variations are equivalent for analytical purposes).

At the district court, Barr proffered three independent theories under which it sought to invalidate claim 7 of the '549 patent for obviousness-type double patenting. On appeal, we limit our analysis to claim 1 of the '895 patent. We begin by construing claim 1 of the '895 patent and claim 7 of the '549 patent to determine whether the former covers subject matter subsequently claimed in the latter. Claim 1 of the '895 patent pertains to a method of treating depression in humans by administering a compound within the class of compounds defined by the following formula:



wherein each R' is independently hydrogen or methyl; wherein R is naphthyl or



wherein R" and R'" are halo, trifluoromethyl, C_1-C_4 alkyl, C_1-C_3 alkyloxy or C_3-C_4 alkenyl; and wherein n and m are 0, 1 or 2; and acid addition salts thereof formed with a pharmaceutically-acceptable acid.

Claim 7 of the '549 patent claims a method for administering the compound fluoxetine hydrochloride to inhibit serotonin uptake. Claim 7 depends on claim 4, which claims a method of blocking the uptake of monoamines by administering a compound found within the same class of compounds that is defined by claim 1 of the '895 patent. Thus, fluoxetine hydrochloride covered in claim 7 of the '549 patent is also one of the compounds encompassed by claim 1 of the '895 patent. It necessarily follows that claim 1 of the '895 patent covered the administration of fluoxetine hydrochloride to treat depression.

Lilly argues that selecting fluoxetine hydrochloride from the class of compounds in claim 1 of the '895 patent to treat depression would not have been obvious to one of ordinary skill in the art because that claim covers thousands of possible compounds. That argument, however, is of no consequence because double patenting is not "concerned with what one skilled in the art would be aware [of] from reading the claims but with what inventions the claims define." *In re Sarett*, 327 F.2d 1005, 1013,

140 USPQ 474, 481 (CCPA 1964). Here, claim 1 of the '895 patent, when properly construed, already covered the administration of fluoxetine hydrochloride for treating depression. Further, Lilly's reliance on *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994), and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), is unavailing. In those cases, we held that a species claim is not necessarily obvious in light of a prior art disclosure of a genus. *See Baird*, 16 F.3d at 382, 29 USPQ2d at 1552; *Jones*, 958 F.2d at 350, 21 USPQ2d at 1943. The present case, however, in which the same party *claims* a genus in an earlier patent and then *claims* a species in a later patent is entirely different from cases such as *Baird* and *Jones*, in which the prior art merely *discloses* a genus and a later patent claims a species.

Moreover, we find Lilly's argument to be disingenuous because it seeks to use the broad coverage of claim 1 of the '895 patent as both a sword and a shield. Throughout the term of the '895 patent, by virtue of claim 1's broad coverage, Lilly possessed the right to exclude other parties from administering any of the thousands of claimed compounds, including but not limited to fluoxetine hydrochloride, to treat depression. Thus, for example, if another party attempted to use fluoxetine hydrochloride to treat depression, Lilly could have sued for infringement of the '895 patent or asserted its patent as a dominating patent, *see In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 682 (Fed. Cir. 1986) (explaining that domination exists when a broad claim of an earlier patent reads on a narrower claim of a later patent, such that a party cannot practice the later patent without infringing the earlier patent). As a corollary to that

expansive right of exclusivity, the '895 patent specification satisfied the written description requirement by allowing persons of ordinary skill in the art "to recognize that the [inventor] invented what is claimed," *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989), and the enablement requirement by providing a specification that taught one of ordinary skill in the art "how to make and use the invention as broadly as it is claimed," *In re Goodman*, 11 F.3d 1046, 1050, 29 USPQ2d 2010, 2013 (Fed. Cir. 1993) (quoting *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991)). With the '895 patent now expired, Lilly cannot hide behind its once-advantageous broad coverage, disavow its prior compliance with the written description and best mode requirements, and argue that selecting fluoxetine hydrochloride from the class of compounds defined by claim 1 of the '895 patent would not have been obvious.

Having construed claim 1 of the '895 patent and claim 7 of the '549 patent and concluded that the use of fluoxetine hydrochloride is covered by the earlier claim, we must next determine whether there are any differences between the two claims that are ~~patentably distinct.~~ *See Georgia-Pacific*, 195 F.3d at 1327, 52 USPQ2d at 1595; *General Foods*, 972 F.2d at 1279, 23 USPQ2d at 1844. The only discernible difference between claim 1 of the '895 patent and claim 7 of the '549 patent is that the former addresses the treatment of depression in humans while the latter addresses the treatment of serotonin uptake in animals. Humans are a species of the animal genus, and depression is a species ailment of the genus of ailments caused by defective serotonin uptake. Our case law

firmly establishes that a later genus claim is not patentable over an earlier species claim. *See In re Berg*, 140 F.3d 1428, 1437, 46 USPQ2d 1226, 1233 (Fed. Cir. 1998) (affirming the rejection of genus claims in a later patent application for obviousness-type double patenting in light of species claims in an earlier patent); *In re Lonardo*, 119 F.3d 960, 967, 43 USPQ2d 1262, 1267 (Fed. Cir. 1997) (invalidating claims in later patent for obviousness-type double patenting when "many of the alleged differences in elements are in species-genus form," with the earlier patent claiming elements more specifically and the later patent claiming elements more generally); *Goodman*, 11 F.3d at 1053, 29 USPQ2d at 2016; *In re Vogel*, 422 F.2d 438, 442, 164 USPQ 619, 622-23 (CCPA 1970) (affirming a rejection of a claim in a later patent covering a method for packaging meat as obviousness-type double patenting in light of claims in an earlier patent covering a method for packaging pork); *see also Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894) (reasoning that a later patent "containing a broader claim, more generical [sic] in its character than the specific claim in the prior patent" is void); *Gosteli*, 872 F.2d at 1010, 10 USPQ2d at 1616 (holding that earlier species invention anticipates later generic claim); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claim). Accordingly, we hold that the differences between claim 1 of the '895 patent and claim 7 of the '549 patent are not patentably distinct.

Furthermore, the circumstances giving rise to the present case support our conclusion that claim 7 is invalid for obviousness-type double patenting. This case arose when Barr filed an ANDA application seeking FDA

approval for marketing fluoxetine hydrochloride as an antidepressant, and Lilly responded by suing for infringement of, *inter alia*, claim 7 of the '549 patent. Under the '895 patent, which issued in 1977 and expired in 1994, Lilly possessed the right to exclude others from administering any compound, including fluoxetine hydrochloride, within the class of claimed compounds to treat depression. In effect, under the '895 patent, Lilly had the right to exclude others from engaging in the very conduct for which Barr currently seeks FDA approval. Now, by asserting claim 7 of the '549 patent, Lilly attempts to extend the term of exclusivity it enjoyed under the '895 patent for an additional nine years beyond the statutorily prescribed term. "Effectively extending the patent term, however, is precisely the result that the doctrine of obviousness-type double patenting was created to prevent." *Berg*, 140 F.3d at 1435, 46 USPQ2d at 1232.

IV. CONCLUSION

In sum, because we hold that claim 5 of the '081 patent and claim 7 of the '549 patent comply with the best mode requirement and that claim 7 is invalid for obviousness-type double patenting, we affirm-in-part and reverse-in-part. Also, because we do not reach the issue, we vacate the district court's grant of a jury trial to Barr.

AFFIRMED-IN-PART,
REVERSED-IN-PART, AND VACATED.

COSTS

Each party bears its own costs.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, vs. BARR LABORATORIES, INC., APOTEX, INC., INTERPHARM, INC., BERNARD C. SHERMAN and GENEVA PHARMACEUTICALS, INC., Defendants.	)	IP 96-0491-C-B/S

ENTRY

This matter comes before the Court on the parties' cross-motions for summary judgment as to Defendants' assertion that claim 7 of Plaintiff's United States Patent No. 4,626,549 (the "'549 patent") is invalid for double patenting. For the reasons set forth below, we *deny* Defendants' motion for summary judgment and *grant* Plaintiff's motions for summary judgment as to Defendants' double patenting defense.

BACKGROUND[1]

On April 10, 1996, Plaintiff Eli Lilly and Company ("Lilly") filed this action against Defendant Barr

[1] The factual background of this case is abbreviated here in the interest of efficiency. The relevant facts forming the background of the present litigation have been addressed in several companion entries that are being released at the same

Laboratories, Inc. ("Barr") seeking a declaratory judgment that Barr was infringing two of its patents – U.S. Patent No. 4,314,081 (the "'081 patent") and U.S. Patent No. 4,626,549 (the "'549 patent"). On June 23, 1997, Plaintiff also filed an action against Defendant Geneva Pharmaceuticals, Inc. ("Geneva") seeking a declaratory judgment that Geneva was infringing the same two patents. On September 18, 1997, Lilly filed an Amended Complaint adding ANDA-related counts against additional Defendants Apotex, Inc. ("Apotex") and Bernard C. Sherman ("Sherman"). The actions were consolidated on October 17, 1997.

This patent infringement lawsuit was prompted by the filing of Abbreviated New Drug Applications by Defendants seeking FDA permission to market generic versions of the antidepressant drug Prozac®, which is currently protected by two patents owned by Lilly. The patents at issue, claim 5 of the '081 patent and claim 7 of the '549 patent, are directed to the active ingredient in Prozac®, fluoxetine hydrochloride, and its use to inhibit serotonin uptake in brain neurons.

Several patents are implicated by the parties' motions for summary judgment, including:

> 1) The '549 patent: Claim 7 of the '549 patent deals with a method of blocking the reuptake of the brain chemical serotonin by brain neurons in

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time as this entry, and we hereby incorporate those factual summaries into this entry. The Court will set forth in this entry only those facts necessary to address the issues squarely before the Court regarding the pending motions for summary judgment regarding Defendants' double patenting defense.

animals by administering fluoxetine hydrochloride (the active ingredient in Lilly's Prozac® pharmaceutical).

2) United State Patent No. 4,018,895 (the "'895 patent"): The '895 patent claims a method of treating depression in humans by administering any compound of a broad family of related chemical compounds.

3) United States Patent No. 4,194,009 (the "'009 patent"): The '009 patent claims pharmaceutical dosage forms derived from a broad family of related chemical compounds.

4) United States Patent No. 4,314,081 (the "'081 patent"): Claim 5 of the '081 patent claims the chemical compound fluoxetine hydrochloride.

5) United States Patent No. 4,590,213 (the "'213 patent" or the "Stark patent"): Claim 6 of the Stark patent is directed towards a method of treating anxiety in a human subject in need of such treatment comprised of administering to such human an effective amount of fluoxetine hydrochloride.

6) United States Patent No. 4,329,356 (the "'356 patent" or the "Holland patent"): Claim 13 of the Holland patent is directed towards a method for lowering the blood pressure in hypertensive mammals (mammals with high blood pressure) in need of such treatment comprised of administering to such mammals an anti-hypertensive amount of fluoxetine hydrochloride.

SUMMARY JUDGMENT STANDARD

Rule 56(c) of the Federal Rules of Civil Procedure provides that a motion for summary judgment shall be

granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact, and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists if there is sufficient evidence for a jury to return a verdict in favor of the nonmoving party on the particular issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 2510 (1986); *Methodist Med. Center v. American Med. Sec., Inc.*, 38 F.3d 316, 319 (7th Cir. 1994). A disputed fact is material only if it might affect the outcome of the suit in light of the substantive law. *See Anderson*, 477 U.S. at 248, 106 S.Ct. at 2510; *Greenslade v. Chicago Sun-Times, Inc.*, 112 F.3d 853, 857 (7th Cir. 1997). Moreover, "in rendering a decision on a motion for summary judgment, a court must 'view the evidence presented through the prism of the substantive evidentiary burden' that would inhere at trial." *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 880-881 (Fed. Cir. 1998) (quoting *Anderson*, 477 U.S. at 254, 106 S.Ct. at 2513). In considering a summary judgment motion, a court must draw all justifiable inferences in a light most favorable to the opposing party and must resolve any doubt against the moving party. *See Anderson*, 477 U.S. at 255, 106 S.Ct. at 2513; *Spraying Sys. Co. v. Delavan, Inc.*, 975 F.2d 387, 392 (7th Cir. 1992).

While the burden rests squarely on the party moving for summary judgment to show "that there is an absence of evidence to support the nonmoving party's case," *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S.Ct. 2548, 2553 (1986), the nonmoving party may not simply rest on the pleadings, but must affirmatively demonstrate by specific

factual allegations that a genuine issue of material fact exists for trial. *See Celotex*, 477 U.S. at 322-23, 106 S.Ct. at 2552-53; *Billups v. Methodist Hosp. of Chicago*, 922 F.2d 1300, 1302 (7th Cir. 1991). Conclusory allegations by a party opposing a motion for summary judgment cannot defeat the motion. *See Smith v. Shawnee Library System*, 60 F.3d 317, 320 (7th Cir. 1995). "The moving party is 'entitled to a judgment as a matter of law' [if] the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex*, 477 U.S. at 323, 106 S.Ct. at 2253. However, if doubts remain as to the existence of a material fact, those doubts should be resolved in favor of the nonmoving party and summary judgment denied. *See Wolf v. City of Fitchburg*, 870 F.2d 1327, 1330 (7th Cir. 1989).

DISCUSSION

"The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof." *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). The Federal Circuit recognizes two different types of double patenting challenges: "same invention" type double patenting and "obviousness-type" double patenting. *See id.; see also General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278 (Fed. Cir. 1992).

> "Same invention" double patenting is based upon 35 U.S.C. § 102 (1994), which states that an inventor may obtain "a patent" for an invention. The statute thus permits only one patent to be

> obtained for a single invention, and the phrase "same invention" refers to an invention drawn to substantially identical subject matter. Obviousness-type double patenting, on the other hand, is judicially created and prohibits an inventor from obtaining a second patent for claims that are not patentably distinct from the claims of the first patent.

In re Lonardo, 119 F.3d at 965 (citing *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985)). *General Foods* sets forth a basic, two-step inquiry for determining double patenting:

> The opinion in In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970), undertook a "restatement of the law of double patenting as enunciated by this court." To summarize it, the opinion says that the first question is: Is the same invention being claimed twice? If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting. The court was speaking, of course, about the PTO rejection of a pending patent application intended to forestall double patenting. If the rejected claim defines *more* than an obvious variation, it is *patentably distinct.*

972 F.2d at 1278 (emphasis supplied). *General Foods* thus concluded that the appropriate inquiry for determining an obviousness-type double patenting challenge is whether the claimed invention is distinctly patentable. *See id.*

We begin our analysis of the double patenting claim by reminding Barr of the extremely high bar it faces in proving its invalidity defenses. Patents are presumed

valid because they have survived rigorous review by the Patent and Trademark Office (the "PTO") and thus those who challenge the validity of a patent duly issued by the PTO as to arguments the PTO already addressed during the patent prosecution are required to prove the invalidity of such patent by clear and convincing evidence, a high threshold indeed. However, we find in this case that even if the bar were set low for Barr, the evidence it has adduced in support of its double patenting claim would be insufficient to preserve its right to trial on this issue. Barr has not presented evidence allowing us to reach as a matter of deduction the conclusion Barr proposes, nor is the issue one that we are able to determine simply by naked review of the claims of the patents in dispute. Thus, for the reasons set forth below, we are compelled to conclude that Barr has not advanced the necessary factual assertions to survive the entry of summary judgment against it on its double patenting defense.

Barr's primary contention is that claim 7 of the '549 patent is invalid for double patenting because it merely sets forth the "scientific explanation" for the subject matter of certain of Lilly's other patents. Barr's summary judgment briefing on this issue is a confusing amalgamation of broad patent law principles that are not clearly applicable to the issues before the Court. In fact, the only case law cited in support of its theory is a dissenting opinion, never adopted thereafter by any court as best we could determine. Even disregarding any limitation on the application of this legal theory to the issues at hand, we observe that Barr's briefs focus extensively on the formulation and restatement of its legal theory to the exclusion

of any evidence sufficient to explain or support it. Most notably, Barr has failed to provide any authoritative, reliable scientific opinion to establish that claim 7 of the '549 patent constitutes merely the later scientific explanation of what has already been claimed in the patents that came before. In light of this glaring deficiency of Barr's evidentiary record, we *deny* Defendants' motion for summary judgment and *grant* Plaintiff's motions for summary judgment as to Defendants' double patenting defense.

It is so ORDERED this 12th day of January, 1999.

/s/ Sarah Evans Barker
SARAH EVANS BARKER,
CHIEF JUDGE
United States District Court
Southern District of Indiana

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United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ORDER

(Filed Jul. 18, 2001)

A combined petition for panel rehearing and for rehearing en banc having been filed by the CROSS-APPELLANT, and a response thereto having been invited by the court and filed by the APPELLANT*, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

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* Barr Laboratories, Inc. filed the response.

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on July 25, 2001.

Circuit Judge LINN did not participate in the vote.

FOR THE COURT,

/s/ Jan Horbaly (AV)
Jan Horbaly
Clerk

Dated: July 18, 2001

cc: Hugh Moore, Richard Clark, James Hurst
Allen Sokal
W. Mentlik, J. Kushan, N. Linck
J. Mueller, J. Vassil, H. Wamsley

ELI LILLY & CO V BARR LABS, 99-1262, -1263, -1264, -1303
(DCT – 96-CV-0491)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

Judgment

ON APPEAL from the U.S. DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA

In CASE NO(S). 97-CV-1029

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED-IN-PART, REVERSED-IN-PART and VACATED.

ENTERED BY ORDER OF THE COURT

DATED MAY 30 2001 /s/ Jan Horbaly lk
Jan Horbaly, Clerk

ISSUED AS A MANDATE: JUL 26 2001

NOTE: Pursuant to Fed. Cir. R. 47.6 this order is not citable as precedent. It is a public order.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ON MOTION

Before MAYER, *Chief Judge*, FRIEDMAN, *Senior Circuit Judge*, and GAJARSA, *Circuit Judge*.

ORDER

Eli Lilly and Company (Lilly) moves to stay issuance of the mandate pending the filing of a petition for writ of certiorari at the Supreme Court of the United States. Lilly

advises that the appellants indicate that they will oppose this request.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.

FOR THE COURT,

JUL 26 2001
Date

/s/ Jan Horbaly (AV)
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Richard S. Clark, Esq.
James F. Hurst, Esq.
Hugh L. Moore, Esq.
Herbert C. Warnsley, Esq.
William L. Mentlik, Esq.
John C. Vassil, Esq.
Janice M. Mueller, Esq.
Nancy J. Linck, Esq.
Jeffrey P. Kushan, Esq.

FILED
U.S. COURT
OF APPEALS FOR
THE FEDERAL CIRCUIT
JUL 26 2001
JAN HORBALY
CLERK

35 U.S.C. § 100(b)

The term "process" . . . includes a new use of a known process . . . , composition of matter, or material.

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35 U.S.C. § 101

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

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35 U.S.C. § 102

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

. . . .

(g) . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.

---

35 U.S.C. § 103

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

. . . .

(c) Patentability shall not be negatived by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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35 U.S.C. § 253

A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.

In like manner, any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.